Tec 5 Continuous Flow Vaporizer

Operation and Maintenance Manual

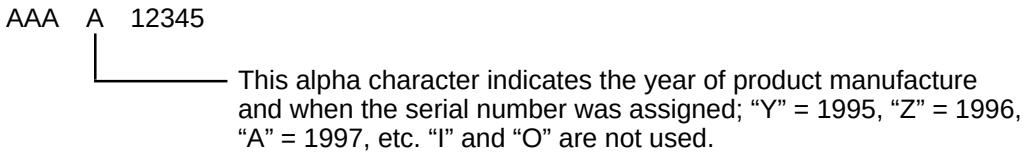
User Responsibility

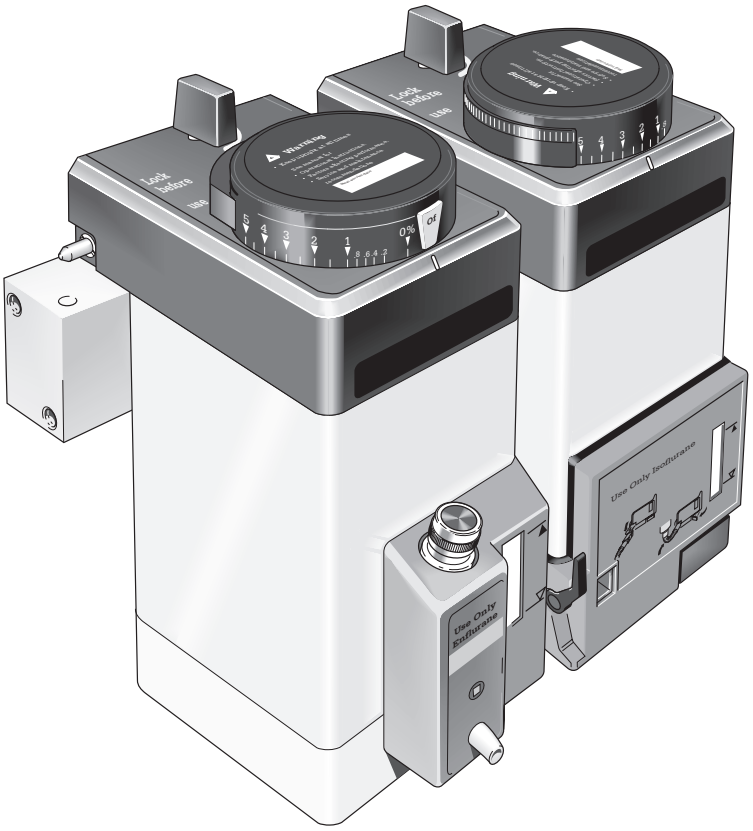
This Product will perform in conformity with the description thereof contained in this operating manual and accompanying labels and/or inserts, when assembled, operated, maintained and repaired in accordance with the instructions provided. This Product must be checked periodically. A defective Product should not be used. Parts that are broken, missing, plainly worn, distorted or contaminated should be replaced immediately. Should such repair or replacement become necessary, Datex-Ohmeda recommends that a telephonic or written request for service advice be made to the nearest Datex-Ohmeda Field Service Support Center. This Product or any of its parts should not be repaired other than in accordance with written instructions provided by Datex-Ohmeda and by Datex-Ohmeda trained personnel. The Product must not be altered without the prior written approval of Datex-Ohmeda's Quality Assurance Department. The user of this Product shall have the sole responsibility for any malfunction which results from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than Datex-Ohmeda.

CAUTION

⚠ U. S. Federal and Canadian law restrict this device to sale by or on the order of a licensed medical practitioner. Outside the U. S. A. and Canada, check local laws for any restrictions that may apply.

Datex-Ohmeda products have unit serial numbers with coded logic which indicates a product group code, the year of manufacture and a sequential unit number for identification.


AAA A 12345
This alpha character indicates the year of product manufacture and when the serial number was assigned; "Y" = 1995, "Z" = 1996, "A" = 1997, etc. "I" and "O" are not used.



Tec 5 Continuous Flow Vaporizer

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1.0 Introduction

1.1 Operation And Maintenance Manual

This Operation And Maintenance (O&M) Manual contains the information required in order to install, operate and maintain the Tec 5 Continuous Flow Vaporizer.

Requests for servicing facilities, advice or assistance must be addressed either to a local Datex-Ohmeda Field Operations Unit or to an Datex-Ohmeda Authorised Distributor.

Additional copies of this manual, quoting Tec 5 Continuous Flow Vaporizer O & M Manual Part No. 1105-0100-000, can be requested from a local Datex-Ohmeda Field Operations Unit or from an Datex-Ohmeda Authorised Distributor.

It is recommended that all relevant documentation, including the O & M Manual and accompanying labels and/or inserts, is immediately available to all prospective operators.

1.2 Precautions

A number of Warnings and Cautions are used throughout this manual to draw attention to the possible hazards and/or adverse conditions which may occur if the information and instructions provided are not strictly observed.

Cautions and Warnings are preceded by ⚠ symbol and are used to draw attention to a condition which can endanger either the patient or the operator and can result in damage to the equipment.

Special attention must be paid to each Warning and Caution as it appears in the manual.

1.3 Symbols

CE Systems with this mark agree with the European Council Directive (93/42/EEC) for Medical Devices when they are used as specified in their operation and maintenance manuals. The xxxx is the certification number of the Notified Body used by Datex-Ohmeda's Quality Systems.

CE European Union Representative

2.0 Servicing Policy

During initial installation of a Tec 5 vaporizer, the Next Service Date label located on the vaporizer dial must be completed by the Technician/Engineer/Customer responsible for the installation.

Datex-Ohmeda recommends that all Tec 5 Vaporizers are serviced every three years, irrespective of conditions of use.

Servicing procedures for this Product must be performed by Datex-Ohmeda trained personnel in accordance with written instructions provided by Datex-Ohmeda.

⚠ **Warning: Only Technicians/Engineers trained and certificated by Datex-Ohmeda to repair and/or service the Tec 5 Vaporizer should attempt to repair and/or service it and it must be repaired and/or serviced at an Datex-Ohmeda Authorised Service Centre in accordance with written instructions provided by Datex-Ohmeda. Detailed information for more extensive repairs is included in the Tec 5 Vaporizer Service Centre Manual which is available only to Authorised Service Centres.**

Warranty repair and service procedures must be performed at an Datex-Ohmeda Authorised Service Centre. A Datex-Ohmeda Service Representative can be contacted at the nearest Datex-Ohmeda Field Operations Unit or Datex-Ohmeda Authorised Distributor.

Do not use malfunctioning equipment. If any assistance is required, contact the nearest Datex-Ohmeda Field Operations Unit or Datex-Ohmeda Authorised Distributor.

If the equipment is to be transported to the nearest Datex-Ohmeda Field Operations Unit, drain the vaporizer, package it securely for protection in its original packaging and ship it prepaid. Enclose the following items as applicable:

1. A letter describing in detail any difficulties experienced with the equipment.
2. Warranty information, such as a copy of the invoice or other applicable documentation.
3. Purchase order number to cover repair of equipment not under warranty.
4. Ship to and bill to information.
5. The name and telephone number of the person to contact.

3.0 Description

3.1 General

⚠ **Warning: This manual and all its associated documentation must be studied thoroughly before any attempt is made to install, operate or maintain any part of the Tec 5 Vaporizer.**

The Tec 5 Vaporizer is designed for out of circuit use in continuous flow techniques of inhalation anaesthesia.

The vaporizer is temperature, flow and pressure compensated so that its output remains relatively constant despite cooling due to evaporation, variations in inlet flow and fluctuating pressures as described in Section 7.2 Effect of Variables.

Each vaporizer is agent specific and is clearly labelled with the name of the anaesthetic agent for which it is designed.

The vaporizer is designed to be used on Selectatec Series Mounted Manifolds. The vaporizer can be installed on other Selectatec Manifolds but the interlock system is designed to function on Selectatec Series Mounted Manifolds only.

Mounting a Tec 5 vaporizer on a Selectatec 7 Compatibility Block is not recommended.

"It is a requirement of European Standard prEN 740 - Anaesthetic Workstations And Their Modules, that an appropriate gas monitor is used to monitor the concentration of anaesthetic agent vapour in the inspiratory gas when the vaporizer is in operation, in order to provide protection against hazardous output in the event of a device malfunction".

⚠ **Warning: If the vaporizer has been inverted, connect it to a gas scavenging system, set the dial to 5% and purge the vaporizer with the carrier gas at 5 litres/minute for 5 minutes.**

⚠ **Caution: Although the vaporizer incorporates an integral non-spill system, the vaporizer is intended to be operated in its upright position.**

⚠ **Caution: Turn the Vaporizer OFF when it is not in use.**

3.2 Control Dial

A single control dial with a concentration scale calibrated in percentage of anaesthetic agent vapour per total volume (% v/v) is employed to set the desired concentration of the anaesthetic agent.

A dial release is incorporated in the dial assembly to prevent accidental displacement of the control dial from the OFF position. To select an ON setting it is necessary to pull in the dial release and simultaneously rotate the dial counter-clockwise.

The dial and dial release are designed to enable an ON setting to be selected using only one hand.

3.3 Safety Interlocks

The vaporizer incorporates an interlock mechanism. This mechanism also interfaces with the Selectatec Series Mounted Manifold to comprise an interlock system which is designed to help ensure that the following criteria are satisfied:

1. The vaporizer must be locked on to the manifold before it can be turned ON.
2. Only one vaporizer at a time can be turned ON when two or more Tec 4, Tec 5 or Tec 6 vaporizers are fitted on a Selectatec Series Mounted Manifold.
3. The gas flow enters only the vaporizer which is turned ON.
4. Any unwanted anaesthetic trace vapour is minimised after a vaporizer is turned OFF.

⚠ **Warning: Earlier versions of the Selectatec Series Mounted Manifold which provide mounting positions for three vaporizers require that if only two vaporizers are fitted then the centre position must be occupied. If the centre position is not occupied the interlock which helps to ensure that only one vaporizer at a time can be turned ON is ineffective.**

Later versions of the Selectatec Series Mounted Manifold which provide mounting positions for three vaporizers incorporate an additional interlock which helps to ensure that only one vaporizer at a time can be turned ON even if the centre position is not occupied.

3.4 Vaporizer Identification Label

A vaporizer identification label is affixed to the back panel of the vaporizer as illustrated on Fig. 1.

An anaesthesia system fitted with a vaporizer identification unit uses this label to identify the vaporizer type.

Do not affix any additional labels or markings to the back panel, they may adversely affect the operation of the vaporizer identification unit.

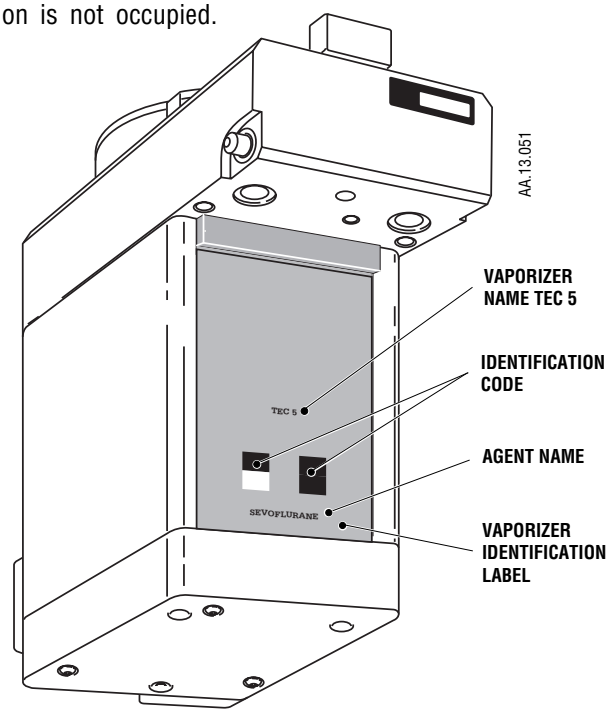


Fig. 1 Vaporizer Identification Label

4.0 Operating Instructions

4.1 General

The vaporizer is designed to be used on Selectatec Series Mounted Manifolds. The vaporizer can be installed on other Selectatec Manifolds but the interlock system is designed to function on Selectatec Series Mounted Manifolds only.

Mounting a Tec 5 vaporizer on a Selectatec 7 Compatibility Block is not recommended.

⚠ **Warning: It is a requirement of European Standard prEN 740 - Anaesthetic Workstations And Their Modules, that the gas monitoring device referred to at 3.1 of this manual is in operating condition, by being enabled and functioning , prior to use of the vaporizer.**

⚠ **Warning: Handle the vaporizer with care at all times. Do not lift or support the vaporizer by holding the control dial.**

⚠ **Warning: Before mounting a vaporizer on to the manifold ensure that only one 'O' ring is fitted to each manifold port valve. Ensure that each 'O' ring is intact and that there is no foreign matter around the mating surfaces. A damaged 'O' ring and/or foreign matter around the mating surfaces can cause leaks.**

⚠ **Warning: Do not use a vaporizer if the liquid level decreases to below the minimum level.**

⚠ **Warning: Before using a vaporizer allow it to attain the ambient temperature of the location in which it is to be used.**

4.2 Vaporizer Mounting Procedure

1. Remove the red coloured dust caps fitted to the vaporizer interlock block ports, illustrated on Fig. 2.

2. Check that each port valve 'O' ring is intact and not damaged. Renew each 'O' ring if necessary.

3. Make sure that the vaporizer control dial is in the OFF position.

4. Make sure that the vaporizer locking lever is at the unlocked position, that is, in the up position.

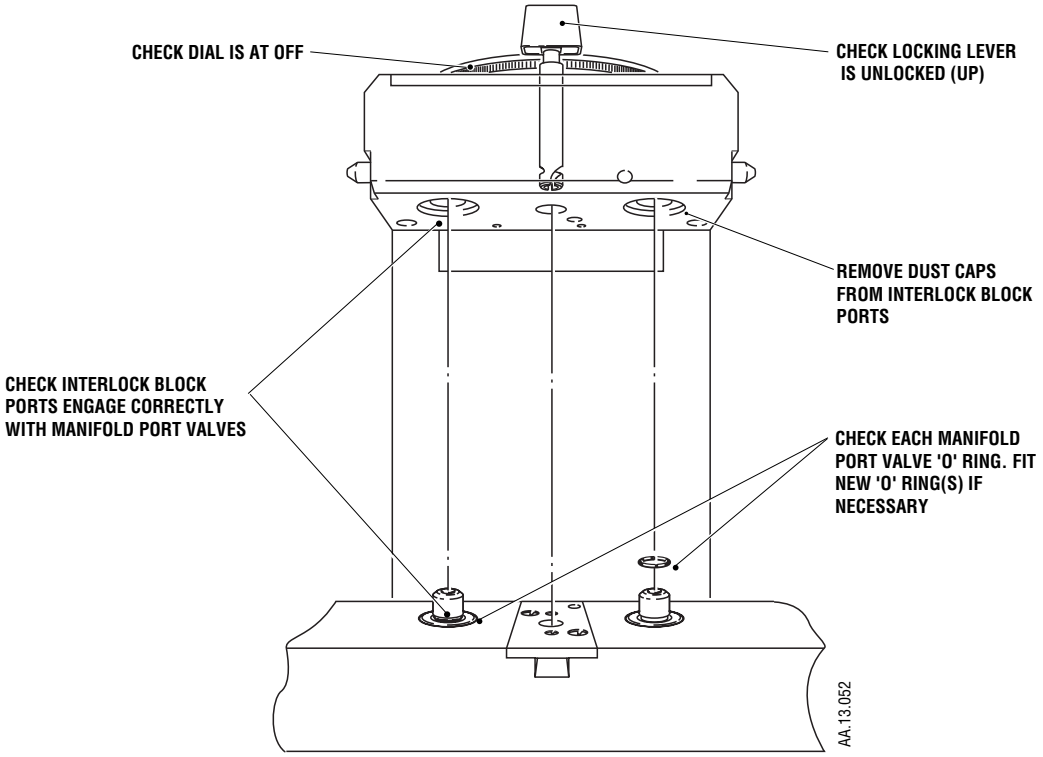

CHECK DIAL IS AT OFF
CHECK LOCKING LEVER IS UNLOCKED (UP)
REMOVE DUST CAPS FROM INTERLOCK BLOCK PORTS
CHECK INTERLOCK BLOCK PORTS ENGAGE CORRECTLY WITH MANIFOLD PORT VALVES
CHECK EACH MANIFOLD PORT VALVE 'O' RING. FIT NEW 'O' RING(S) IF NECESSARY
AA.13.052

Fig. 2 Vaporizer Mounting Procedure

5. Carefully lower the vaporizer on to the manifold so that the vaporizer interlock block covers the two manifold port valves with the interlock block ports correctly engaged with the manifold port valves.

⚠ **Caution: Push the locking lever down to the full extent of its travel before attempting to turn it. The mechanism may be damaged if an attempt is made to turn the lever before it is at the full extent of its vertical travel.**

6. Press down the locking lever ① to the full extent of its travel and then turn it clockwise ② to the locked position ③ to lock the vaporizer on to the manifold as illustrated on Fig. 3.

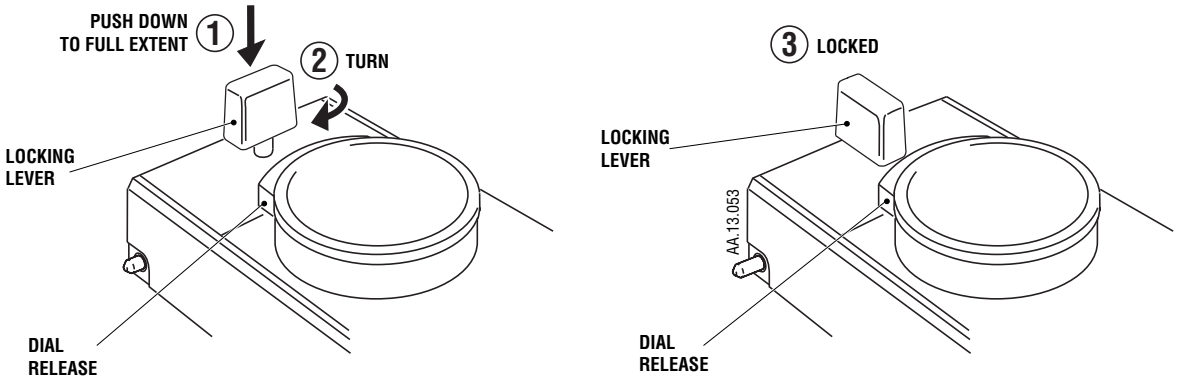


Fig. 3 Locking The Vaporizer On To A Manifold

4.3 Checking For Correct Mounting Of The Vaporizer

⚠ **Warning: To help to ensure correct operation, do not use a vaporizer which is visibly out of line on the manifold or which can be lifted off the manifold when the locking lever is in the locked position.**

1. If more than one vaporizer is fitted, visually check to make sure that the tops of vaporizers are square to the manifold. If a vaporizer is visibly out of line, remove it from the manifold and attempt to mount it correctly. Do not use a vaporizer which cannot be mounted correctly.

2. When the vaporizers appear to be level and their locking levers are in the locked position, attempt to lift each vaporizer from the manifold.

3. If a vaporizer can be lifted OFF the manifold, remove it from the manifold and attempt to mount it correctly. Do not use a vaporizer which cannot be mounted correctly.

4. Make sure only one vaporizer at a time can be turned ON, thus checking that the interlock rods are in alignment.

5. Check the anaesthesia system for leaks in accordance with the relevant O&M Manual with the vaporizer dial turned to 0% and then repeat the check with the vaporizer dial turned OFF.

4.4 Turning ON The Vaporizer

Note: Do not attempt to turn the dial if the vaporizer is not properly locked on to the manifold.

1. Pull in the dial release illustrated on Fig. 4 and rotate the dial counter-clockwise. Note that it is not possible to turn ON the vaporizer if an adjacent Tec 4, Tec 5 or Tec 6 vaporizer is turned ON.

2. The vaporizer should not be used between OFF and the first graduation mark. To avoid inadvertent delivery of small concentrations the control dial should be turned OFF when the vaporizer is not in use.

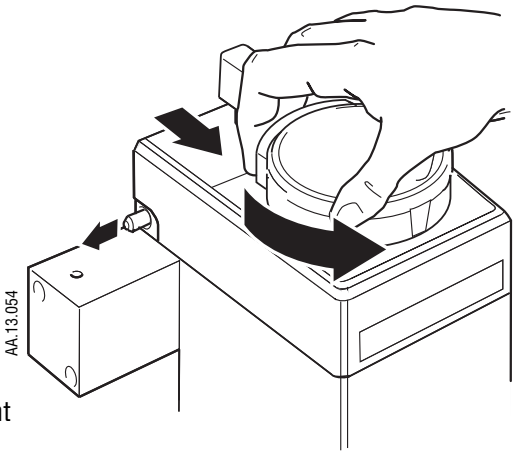


Fig. 4 Turning ON The Vaporizer

4.5 Vaporizer Removal

1. Rotate the dial clockwise to turn OFF the vaporizer. If it is not completely turned to the OFF position it cannot be released from the manifold.

2. Referring to Fig. 5, unlock the vaporizer from the manifold by turning the locking lever ① counter-clockwise to the unlocked position. Release the locking lever ②, check that the locking lever springs up to the unlocked condition ③ and then carefully lift the vaporizer straight up and off the manifold.

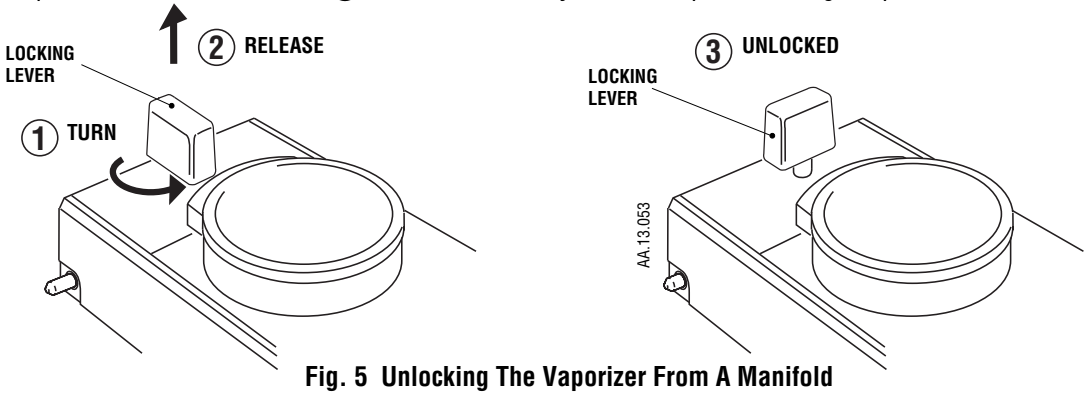


Fig. 5 Unlocking The Vaporizer From A Manifold

4.6 Filling And Draining

4.6.1 General

⚠ **Warning: Do not fill the vaporizer with any agent other than the agent specified on the front label. The vaporizer is designed for that agent only. Filling the vaporizer with any agent other than that specified can prove to be dangerous to a patient.**

⚠ **Warning: Do not fill the vaporizer unless the control dial is in the OFF position.**

⚠ **Warning: Do not turn the dial ON during filling or attempt to fill beyond the ▲ mark.**

⚠ **Warning: Do not drain the agent into any container other than a properly marked drug container.**

⚠ **Warning: Ensure that the filler cap is tightened prior to use.**

Periodically check the agent level. The vaporizer should be refilled at appropriate intervals. The vaporizer is designed to function according to specification as long as there is agent visible above the ▽ mark.

The vaporizer must be filled and used in an upright position. Small deviations from the upright position do not affect either the output or the safety of the vaporizer, but because the agent depth is shallow in relation to the diameter of the vaporizing chamber, more frequent checks of the agent level should be performed to avoid a misleading impression of the amount of agent in the vaporizer when small deviations from the upright position occur.

At intervals, ideally not exceeding two weeks, the vaporizer should be drained into the correct drug bottle when the agent is low. This helps to preserve the drug purity by removing oxidized impurities, accumulated contaminants and stabilisers. Discard the agent in a manner consistent with local policies and guidelines. Less frequent intervals may be used when the anaesthetic agent does not contain additives or stabilising agents.

4.6.2 Filling A Vaporizer Which Incorporates A Screw Cap Filler

⚠ **Warning: Before filling a vaporizer fitted with a screw cap filler, turn the cap slowly to allow any pressure to vent slowly.**

1. Turn the vaporizer dial clockwise to the OFF position.

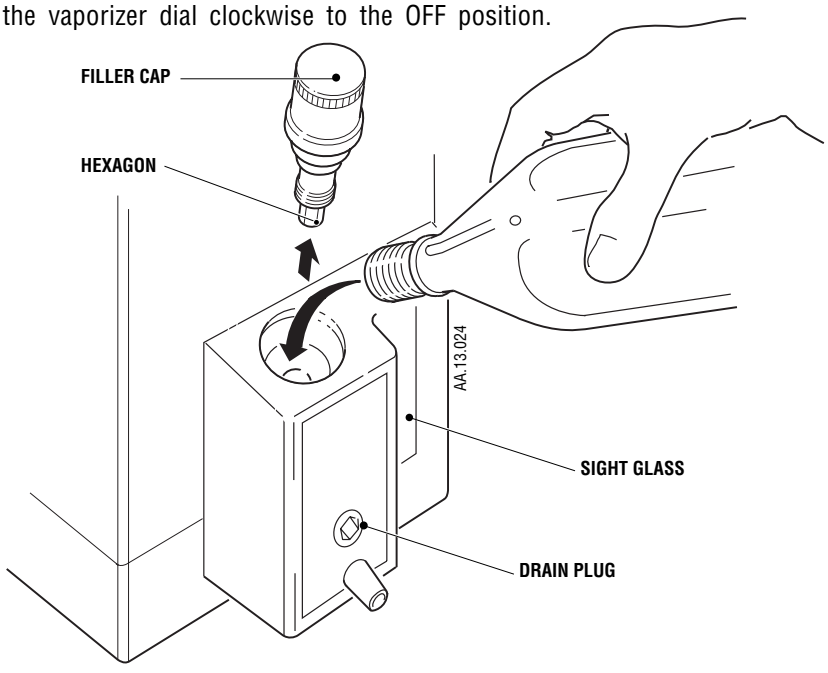


Fig. 6 Filling A Vaporizer Which Incorporates A Screw Cap Filler

2. Remove the filler cap by turning it counter-clockwise. Ensure that the drain plug is closed by tightening it with the hexagonal end of the filler cap.

3. Verify that the anaesthetic agent is the same as that specified on the vaporizer front label. Observe the agent level through the sight glass indicator on the side of the filler body and pour the agent slowly into the filling port, as illustrated on Fig. 6, until the level reaches the mark. The level may decrease slightly as the wicks absorb the agent.

4. Replace the filler cap and tighten it to minimise any possibility of leaks.

4.6.3 Draining A Vaporizer Which Incorporates A Screw Cap Filler

⚠ **Caution: Do not allow a bottle to become completely full during draining procedures.**

The vaporizer must only be drained into a properly marked container, as follows:

1. Remove the filler cap and insert the hexagonal end of the cap into the drain plug situated below the filling port on the filler body as illustrated on Fig. 7.

2. Position a properly marked container under the drain spout.

3. Unscrew but do not remove the drain plug to allow the vaporizer contents to pour from the drain spout into the container.

4. After draining is complete, tighten the drain plug to minimise any possibility of leaks.

5. Replace the filler cap and tighten it to minimise any possibility of leaks.

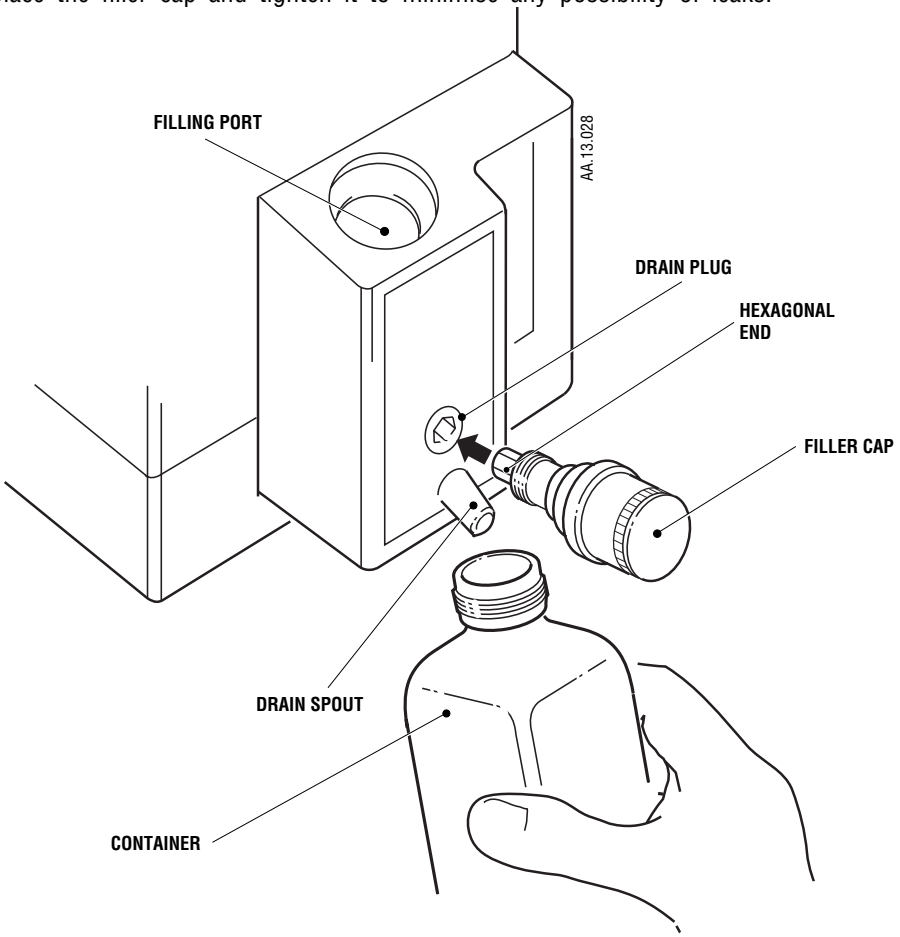


Fig. 7 Draining A Vaporizer Which Incorporates A Screw Cap Filler

4.6.4 Filling A Vaporizer Which Incorporates A Keyed Filler

⚠ **Caution: Always hold the bottle below the level of the end of the bottle adaptor and also below the level of the filler port until the adaptor is clamped into position.**

⚠ **Caution: If it is suspected that there is liquid in the adaptor air tube, remove the bottle adaptor from the bottle and carefully shake the adaptor two or three times to clear the tube.**

The filling system consists of three elements, the bottle collar, the bottle adaptor and the filling and draining unit fitted to the vaporizer. The vaporizer must only be filled using the correct agent specific filling system, as follows:

1. Screw the agent specific bottle adaptor firmly on to the bottle.

2. Ensuring that the bottle (1) is held below the level of the end of the bottle adaptor and below the level of the filler port, insert the end of the bottle adaptor into the filler port (2) as illustrated on Fig. 8.

3. Tighten the locking clamp by pulling the locking clamp lever forward and downward (3) until the bottle adaptor is clamped.

⚠ **Caution: When it is set correctly, the clamp secures the bottle adaptor without using the full travel of the locking lever. The lever must not be forced to its lowest limit of travel.**

4. Raise the bottle above the level of the filler port (4) and then open the filler port valve by pulling the port valve lever forward (5) to its full extent.

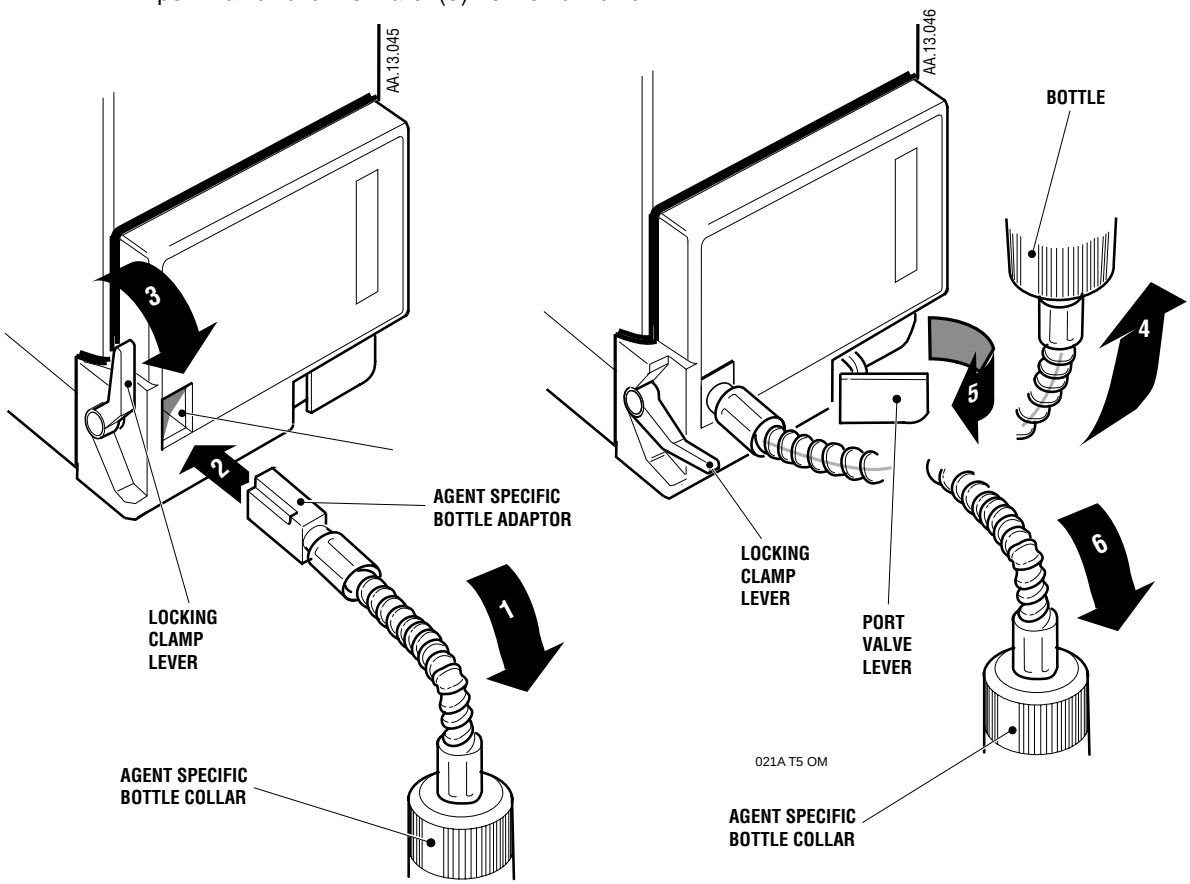


Fig. 8 Filling A Vaporizer Which Incorporates A Keyed Filler

Note: The vaporizer normally fills in less than one minute. If the vaporizer is dry the level decreases slightly as the wick absorbs the agent.

5. When the vaporizer is full, return the port valve lever (5) to the closed condition to close the valve.

6. Lower the bottle to below the level of the filler port (6) and allow any agent in the tube to drain back into the bottle.

7. Release the locking clamp lever, return it to the up position and then remove the bottle adaptor from the filler port.

4.6.5 Draining Vaporizer Which Incorporates A Keyed Filler

⚠ **Caution: Do not allow a bottle to become completely full during draining procedures.**

The vaporizer must only be drained into a properly marked container, as follows:

1. Position the bottle below the level of the filler port and insert the end of the bottle adaptor into the filler port (1) as illustrated on Fig. 9.

2. Tighten the locking clamp by pulling the lever forward and downward (2) until the adaptor is clamped.

3. Open the filler port valve by pulling the lever forward to its full extent (3).

4. Hold the bottle below the level of the filler port to allow the vaporizer contents to flow into the bottle (4).

5. When the vaporizer is drained, close the port valve.

6. Release the locking clamp and return it to the up position.

7. Remove the bottle adaptor from the port.

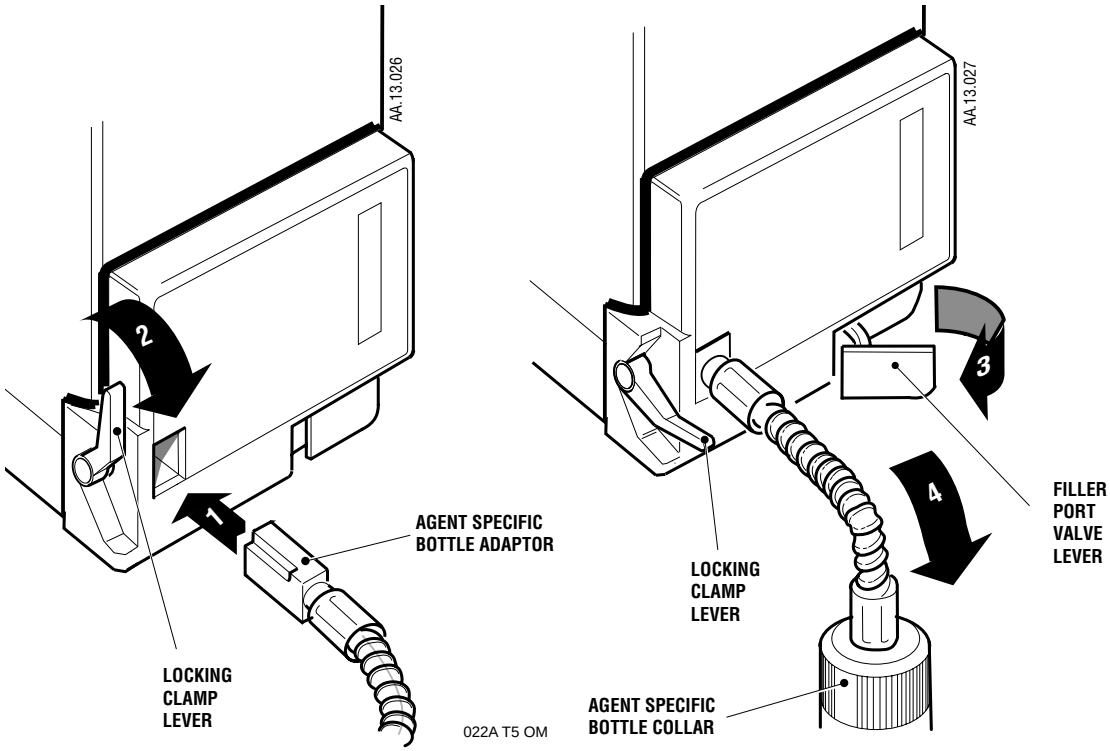


Fig. 9 Draining A Vaporizer Which Incorporates A Keyed Filler

4.6.6 Filling A Vaporizer Which Incorporates A Quik-Fil™ Filler

⚠ **Warning: Ensure that the drain plug screw (1), located on the lower front of the vaporizer, is correctly tightened to prevent loss of liquid agent.**

1. Remove the protective cap from the anaesthetic agent bottle filler, checking that the bottle and filler mechanism are not damaged.

2. Remove the filler cap (2) and insert the bottle nozzle into the filler block. Rotate the bottle to align the bottle filler nozzle keys (3) with the index slots (4) in the filler block as illustrated on Fig. 10.

3. Press the agent bottle fully into the vaporizer filler block. Allow the liquid to flow into the vaporizer until the maximum level mark is reached, paying particular attention to the level in the sight glass and the air return bubbles flowing into the bottle.

4. Release the bottle when the vaporizer is full and the continuous stream of bubbles ceases.

5. Withdraw the bottle from the vaporizer filler and replace the filler cap (2) and the cap on the agent bottle. Ensure that the filler cap is tightened to minimise any possibility of leaks.

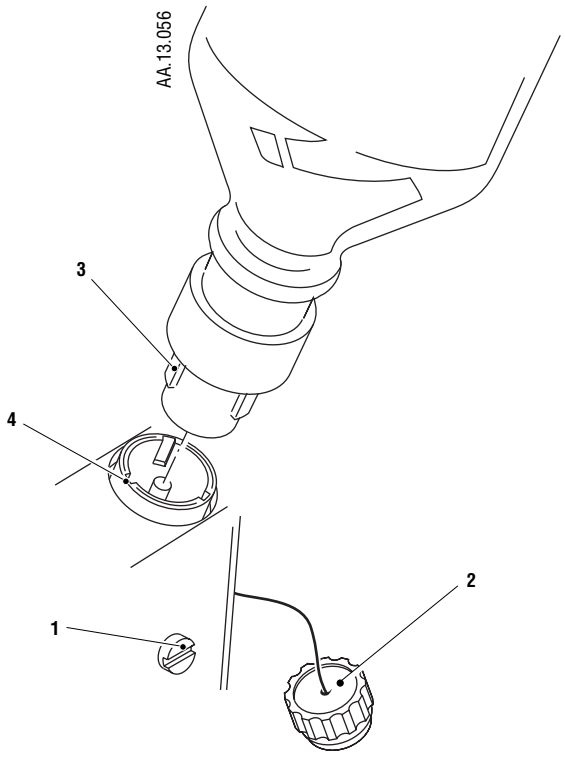


Fig. 10 Filling A Vaporizer Which Incorporates A Quik-Fil™ Filler

4.6.7 Draining A Vaporizer Which Incorporates A Quik-Fil™ Filler

⚠ **Caution: Do not allow a bottle to become completely full during draining procedures.**

The vaporizer must only be drained into a properly marked container, as follows:

1. Remove the cap from the vaporizer filler.

2. Remove the protective cap from an empty bottle. Insert the bottle nozzle into the drain funnel. Rotate the bottle to align the index slots in the drain funnel (1) with the bottle filler nozzle keys (2) and screw the drain funnel onto the empty bottle as illustrated on Fig. 11.

3. Fully insert the drain funnel into the keyed drain slot (3) in the bottom of the vaporizer filler block.

4. Unscrew the drain plug (4) with the key (5). Continue to drain the vaporizer until empty.

5. After draining is complete, tighten the drain plug to minimise the possibility of leaks and withdraw the drain funnel.

6. Replace the filler cap and tighten it to minimise the possibility of leaks.

7. Unscrew the drain funnel from the bottle and refit the protective cap.

Note: If further drain funnels are required they should be obtained from the local Abbott Laboratories representative.

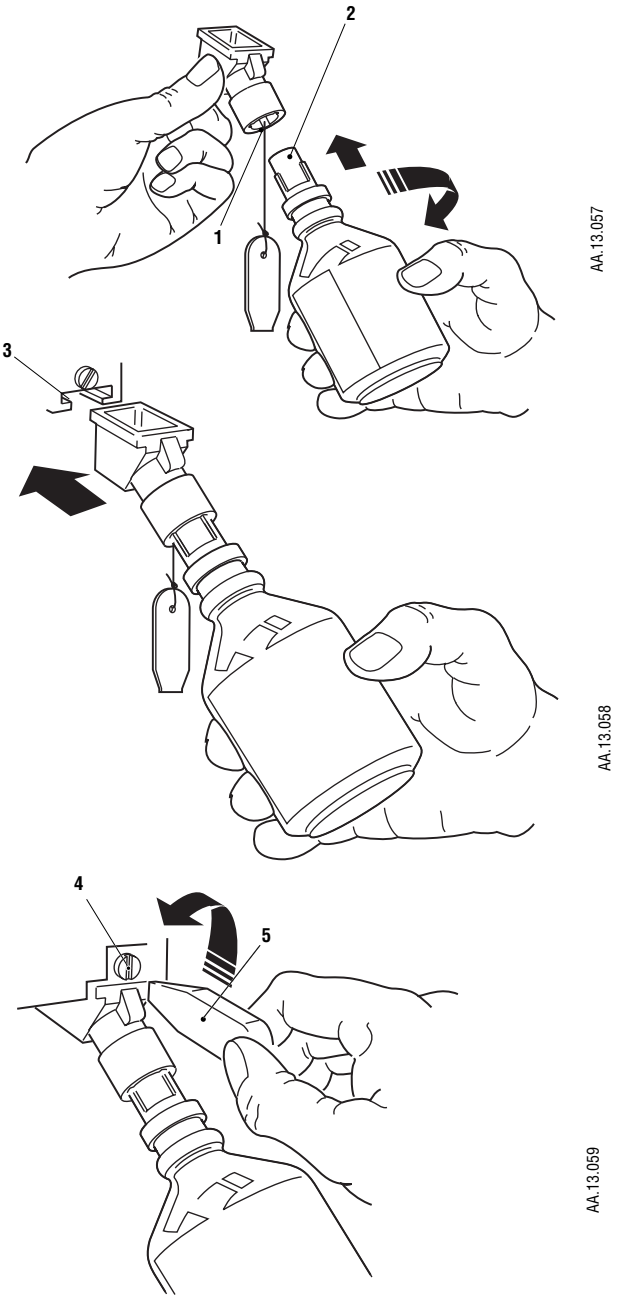


Fig. 11 Draining A Vaporizer Which Incorporates A Quik-Fil™ Filler

5.0 Maintenance

⚠ **Warning: Do not modify, tamper with or disassemble the vaporizer because of the dangers of damaging the unit and altering the accuracy of graduation.**

Observation of the instructions previously provided, regular servicing and normal professional vigilance is normally all that is required to maintain the vaporizer in a safe working condition.

5.1 Schedule

5.1.1 Every Two Weeks

When the agent level is low, drain the contents of the vaporizer into an appropriately marked container and discard the agent. Less frequent intervals may be used when the anaesthetic agent does not contain additives or stabilising agents, but the procedure must be performed at least once every year.

5.1.2 Every Three Years

Datex-Ohmeda recommends that all Tec 5 Vaporizers are serviced every three years, irrespective of conditions of use.

The vaporizer should be serviced at an Datex-Ohmeda authorised Service Centre.

This service includes the following:

1. Complete disassembly of components.
2. Thorough cleaning.
3. Inspection for damage and wear.
4. Renewal of wicks, seals and damaged or worn components.
5. Where appropriate, replacement of discontinued parts with more up-to-date parts.
6. Lubrication where necessary.
7. Checks of delivered vapour concentrations under closely defined conditions at different temperatures and flows with regraduation or adjustment where necessary.

5.2 Cleaning

⚠ **Warning: Do not put water or any other solvent into a vaporizer. A vaporizer should be filled with the specified anaesthetic agent only.**

⚠ **Warning: Do not immerse the vaporizer in any liquid, including water.**

⚠ **Warning: Do not autoclave the vaporizer.**

Clean the exterior of the vaporizer with a damp cloth.

Never allow cleaning agents to accumulate either in the filler, the gas inlet and outlet ports or around the control dial.

5.3 Contamination

If the vaporizer is either filled or partly filled with an incorrect agent or any other contaminant, water for example, proceed as follows:

1. Drain the vaporizer and discard all liquid.

2. Return the vaporizer to a Service Centre stating, if possible, the type of contaminant used.

5.4 Repairs

Repairs must only be performed by the Manufacturer's Service Representatives.

6.0 Principle Of Operation

6.1 Interlock Mechanism

The vaporizer locking lever, illustrated on Fig. 12, is interlocked with the vaporizer percentage control dial in such a way that the control dial release, located at the rear of the dial, cannot be actuated until the vaporizer locking lever is in the locked position.

With the vaporizer locking lever in the locked position the dial release can be pressed in towards the dial to operate the interlock mechanism which simultaneously actuates the following:

1. The interlock extension rods, which extend to minimise the possibility of adjacent vaporizers being turned ON.

2. The two port valve actuating spindles, which actuate the Selectatec Manifold port valves to allow fresh gas to flow through to the vaporizer.

3. The vaporizer percentage control dial release, which allows the dial to be turned to select the required percentage.

Turning the control dial to OFF automatically reverses the operating sequence, which allows the dial release to move out to lock the dial in the OFF position, closes the manifold port valves and vents the vaporizer gas connecting ports and retracts the extension rods to allow an adjacent vaporizer to be turned ON.

Turning the locking lever to the unlocked position releases the vaporizer allowing it to be removed from the manifold.

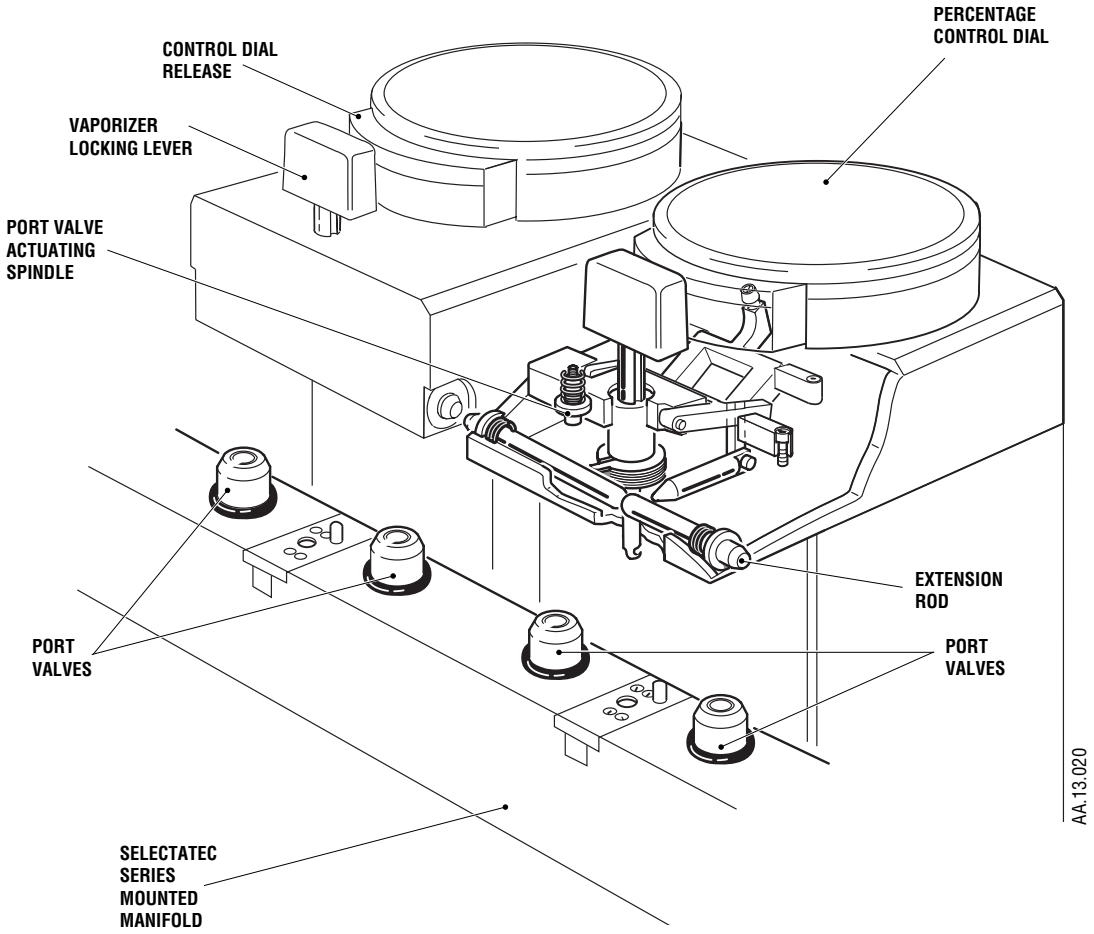


Fig. 12 Vaporizer Interlock Mechanism

When two vaporizers are locked on to a manifold and both are turned OFF as illustrated on Fig. 13, each set of interlock extension rods is retracted allowing either vaporizer to be turned ON.

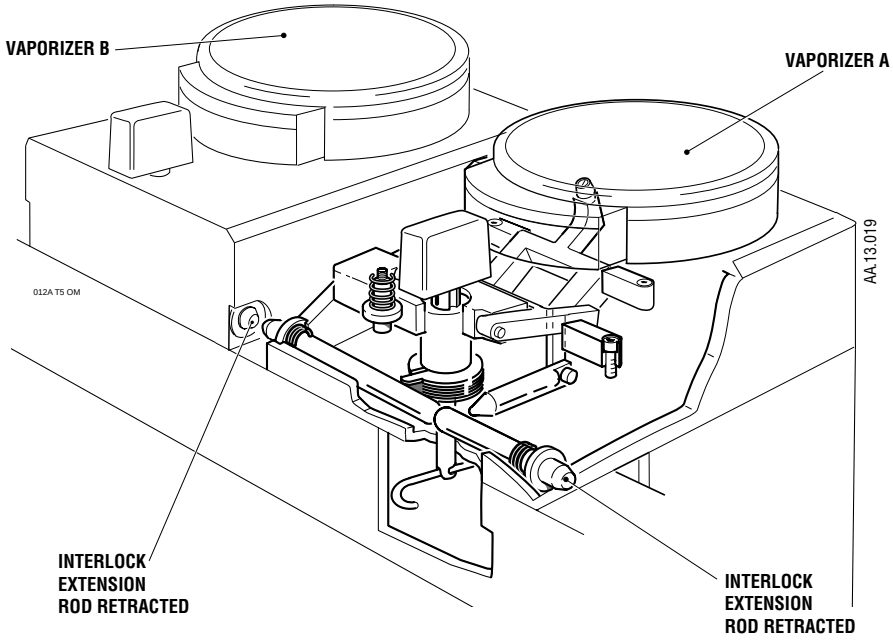


Fig. 13 Two Vaporizers Locked On To The Manifold - Both Turned OFF

Operating the dial release on vaporizer A, illustrated on Fig. 14, extends the interlock extension rods and turning the dial to a % setting locks the extension rods in the extended condition to prevent the possibility of Vaporizer B being turned ON.

The actuating spindles are also operated to open the port valves so that carrier gas can flow through vaporizer A.

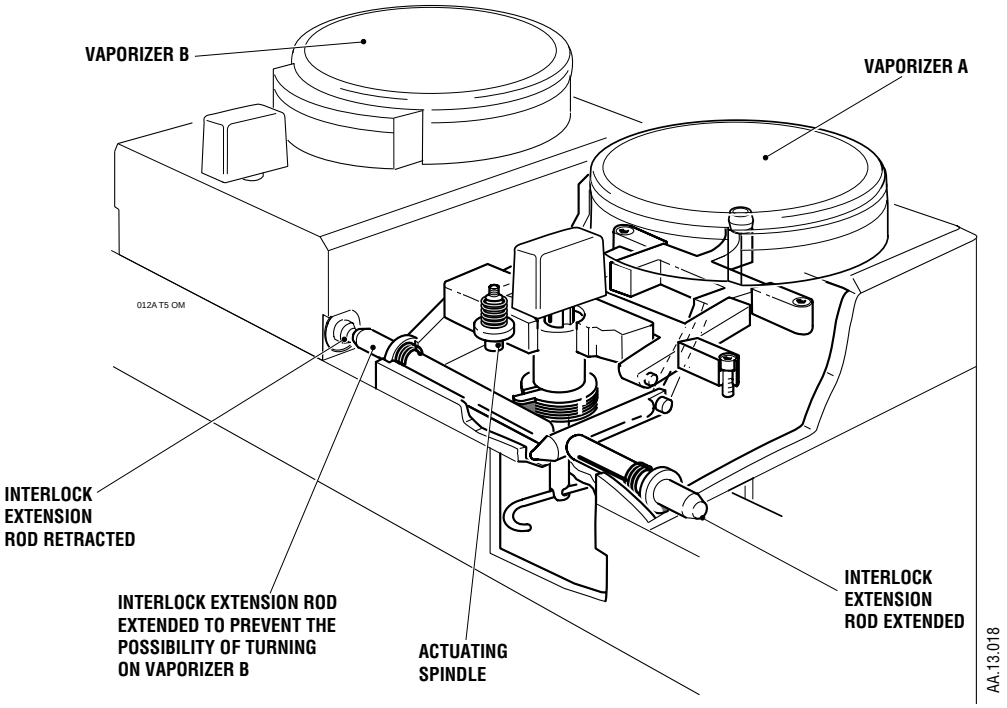


Fig. 14 Two Vaporizers Locked On To The Manifold - Vaporizer A Turned ON

6.2 Selectatec Series Mounted Manifold Gas Circuit

Fresh gas is introduced from the flowmeters into the Selectatec Series Mounted Manifold which incorporate pairs of series-connected, two-way port valves.

When a vaporizer is locked on to a manifold and turned ON, both associated port valves are opened. Fresh gas from the manifold flows into the vaporizer via the inlet port valve and the gas/agent mixture flows from the vaporizer into the manifold via the outlet port valve.

When the vaporizer is turned OFF, or if no vaporizer is fitted, each port valve is closed to provide a seal to atmosphere and also to allow the fresh gas to by-pass the vaporizer via the manifold by-pass circuit.

Vaporizer B illustrated on Fig. 15 is turned OFF, therefore both port valves to which vaporizer B is connected are closed so that the carrier gas flows through the manifold by-pass circuit to vaporizer A.

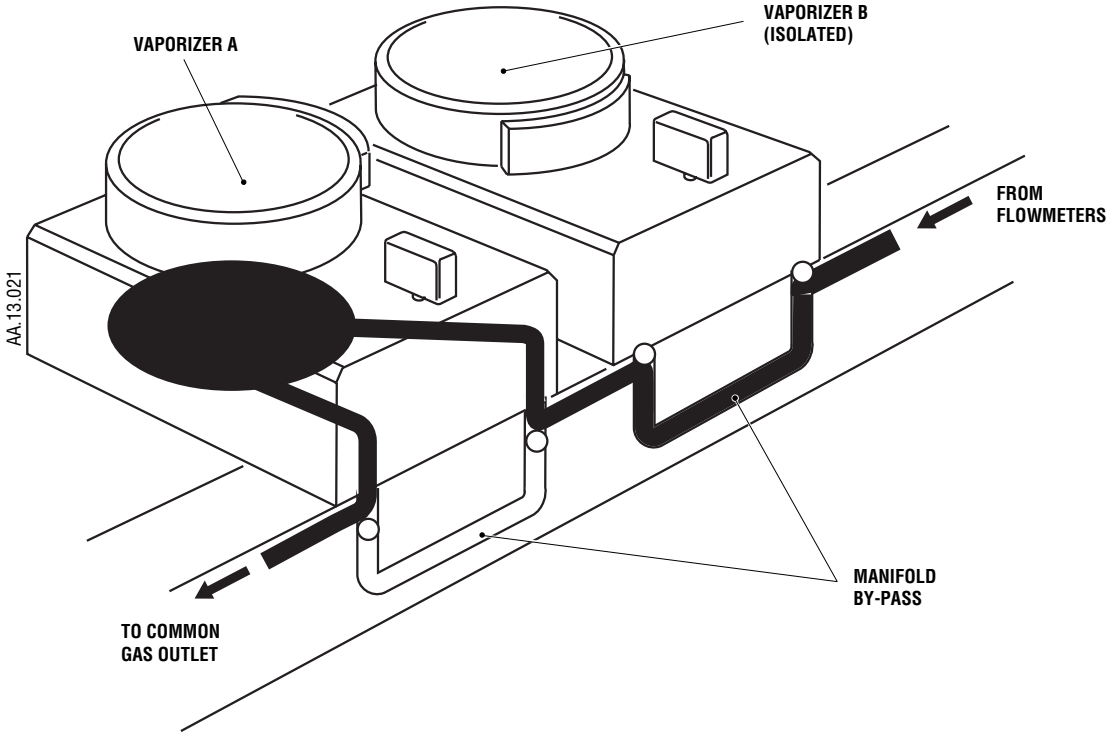


Fig. 15 Manifold By-pass Circuit

Vaporizer A is turned ON therefore both port valves to which vaporizer A is connected are open so that carrier gas flows through the vaporizer to the common gas outlet.

The Selectatec Series Mounted Manifold and the vaporizer connection system previously described forms an interlock system that is designed to allow only one vaporizer at a time to be turned ON. This manifold system accepts Tec 4, Tec 5 and Tec 6 vaporizers.

⚠ **Warning: Connecting any vaporizer other than a Datex-Ohmeda Tec 4, Tec 5 or Tec 6 vaporizer to the Selectatec Series Mounted Manifold defeats the interlock system. This action results in the ability to administer anaesthetic agent mixtures, possibly resulting in patient injury.**

6.3 Vaporizer Valve And Sump Assembly

The vaporizer incorporates a vaporizing chamber and cover assembled between a cover base and an interlock block, and is enclosed by an outer wrap.

A duct system lies within the cover and a rotary valve is located above the cover. The lower face of the rotary valve incorporates ducts and a curved vapour control channel.

The internal baffle system is designed to limit any liquid anaesthetic agent from reaching the valve mechanism if the vaporizer is tilted or even inverted. This system minimises the risk of drug contaminating the valve mechanism and entering the patient circuit.

The spindle of the rotary valve passes through the interlock block and is connected to the control dial.

In the 0% position the rotary valve closes all gas passages except a link between the inlet and outlet within the vaporizer. When the dial is turned past 0% to ON, the carrier gas is split into two streams respectively designated by-pass flow and vaporizing chamber flow.

The vaporizing chamber consists of a woven helical wick which transmits gas flow. Surrounding this helical wick is a woven outer wick which extends below the helical wick into the liquid agent.

The amount of agent picked up in the vaporizing stream can vary, due either to variation in room temperature or to the cooling which takes place when the agent is vaporized. Variation of either temperature or cooling rate can cause changes in the vapour pressures of the anaesthetic agents and unless some form of compensating device is used the output of the vaporizer for a given flow and dial setting can vary with time and temperature.

The vaporizer incorporates a temperature compensating device (thermostat), which utilises a bimetallic strip that deflects according to its temperature to control the resistance offered to the flow of gas through it. This deflection varies the relative proportions of the vaporizing chamber flow and the by-pass flow.

If the temperature of the vaporizer decreases, the thermostat closes, the by-pass flow through the thermostat decreases and therefore the vaporizing chamber flow increases.

Conversely, if the temperature of the vaporizer increases, the thermostat opens, the by-pass flow through the thermostat increases and therefore the vaporizing chamber flow decreases.

Thus the output of the vaporizer remains relatively constant under conditions of changing temperature.

6.4 Gas Flow Through The Vaporizer

6.4.1 General

The output concentration of the Tec 5 vaporizer is regulated by the 'variable flow-split' method described in the following text and illustrated on Fig. 16 and 17:

A total flow of fresh gas from upstream flowmeters enters the vaporizer at ① where it is immediately split into two streams. One stream flows into the fresh gas by-pass circuit and the other stream flows through the vaporizing chamber where it is enriched with the vapour of the liquid anaesthetic agent.

6.4.2 By-pass Circuit

The by-pass circuit includes the gas transfer manifold and also a thermostat assembly which is located at the base of the vaporizer.

The fresh gas flows through the by-pass circuit vertically downwards from ① across the sump base to ⓑ, through the thermostat to ⓒ and back up the gas transfer manifold via ⓓ to ⓔ as illustrated on Fig. 16.

The thermostat deflects according to its temperature to control the resistance offered to the flow of gas through it. This deflection varies the relative proportions of gas flowing through the by-pass and vaporizing chamber circuits, as described in Section 6.3.

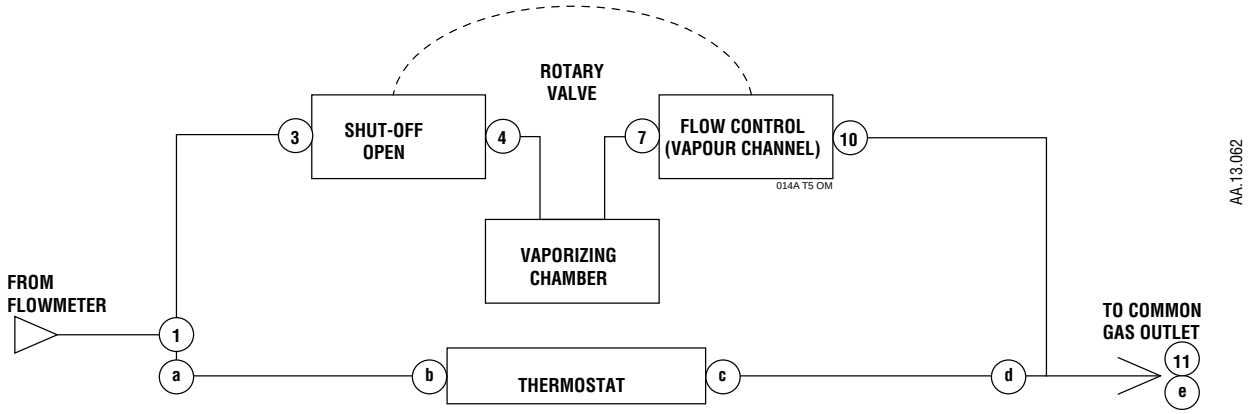


Fig. 16 Vaporizer Flow - Schematic Diagram

6.4.3 Vaporizing Chamber Circuit

The fresh gas flow through the vaporizing chamber, illustrated on Fig. 17, flows from ① across the sump cover ② where it is diverted via ③ through the central cavity of the rotary valve and back through the Intermittent Positive Pressure Ventilation (IPPV) compensating assembly ④, ⑤a and ⑥.

Gas now flows from the IPPV assembly ⑦a down through the tubular wick assembly where it picks up anaesthetic vapour and then flows across the base of the vaporizing chamber above the liquid agent to ⑧.

From the base of the vaporizing chamber the gas/agent mixture flows via ⑨ through the sump cover to the proportional radial drug control groove of the rotary valve and then back into the sump cover ⑩ where it combines ⑪ with the fresh gas from the by-pass circuit.

The combined total flow then flows out from the vaporizer and via the Selectatec circuitry to the anaesthesia system common gas outlet.

With the vaporizer correctly fitted and turned OFF the vaporizer is isolated from the gas flow.

With the vaporizer correctly fitted and turned ON, the gas flow through the vaporizing chamber circuit is via ① through to ⑪ and the gas flow through the by-pass circuit is via ⓐ through to ⓔ.

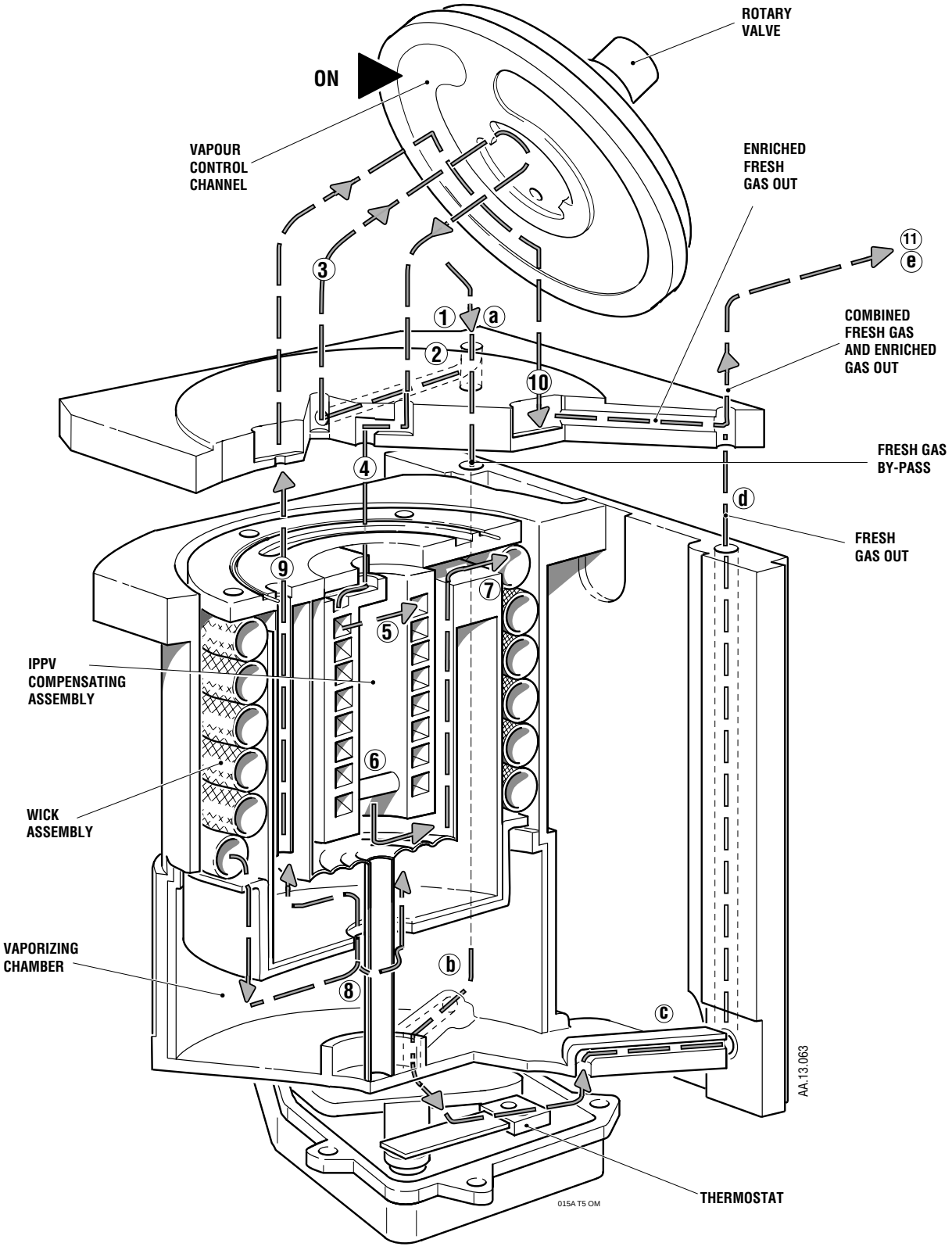


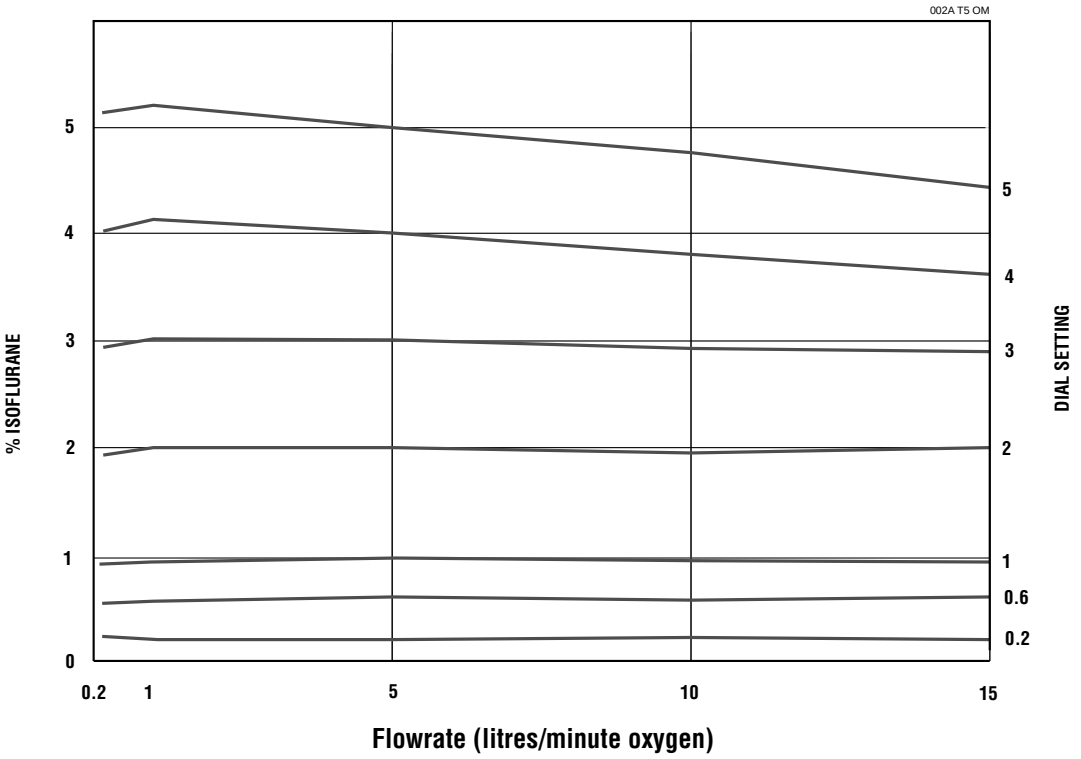
Fig. 17 Tec 5 Vaporizer Gas Flow

7.0 Performance

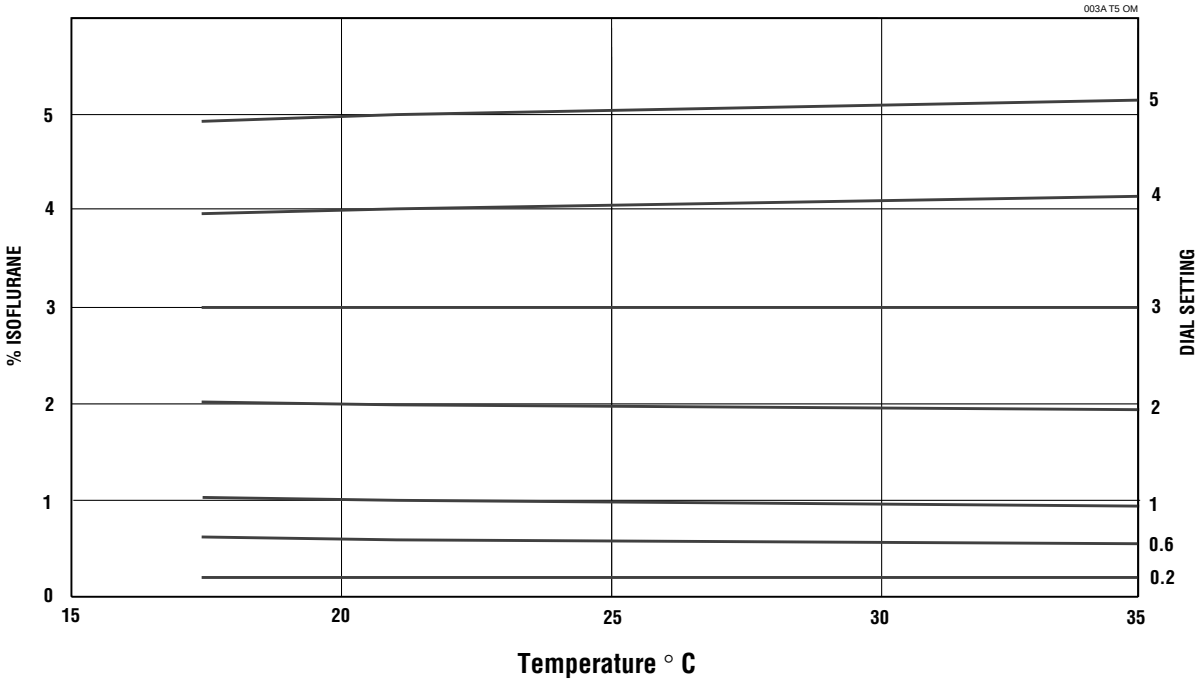
7.1 Performance Curves

7.1.1 Isotec 5%

Effect of Flowrate at 21 ± 2° C with oxygen flowing

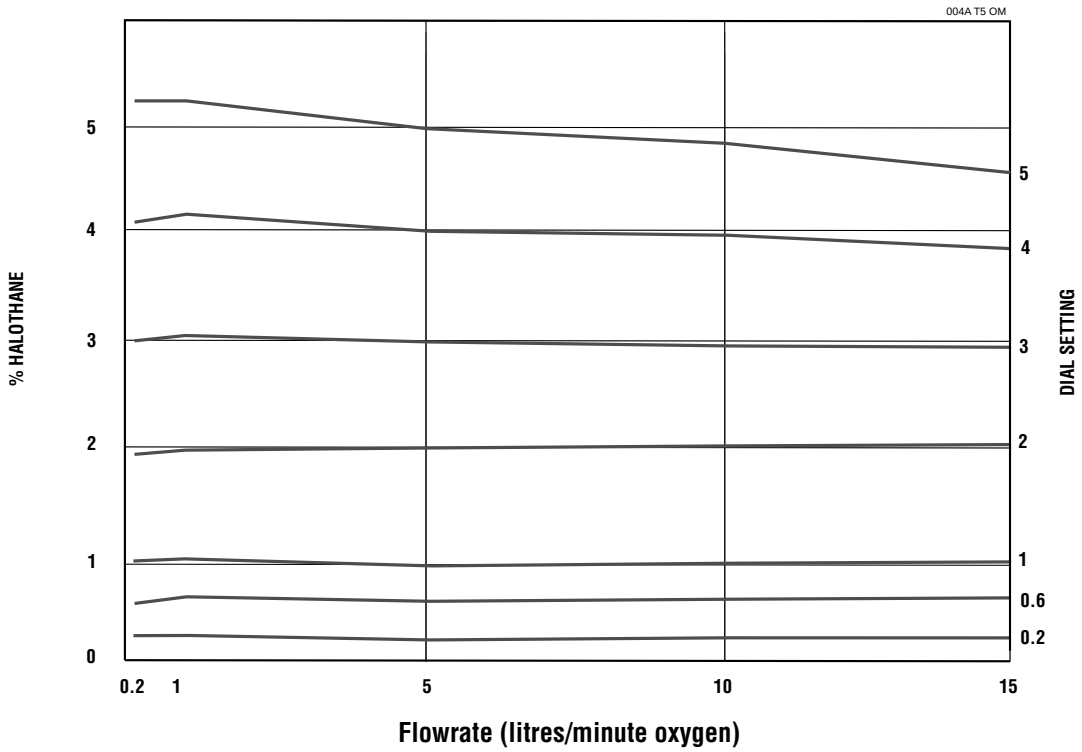


Effect of Temperature at 5 litres/minute oxygen flow

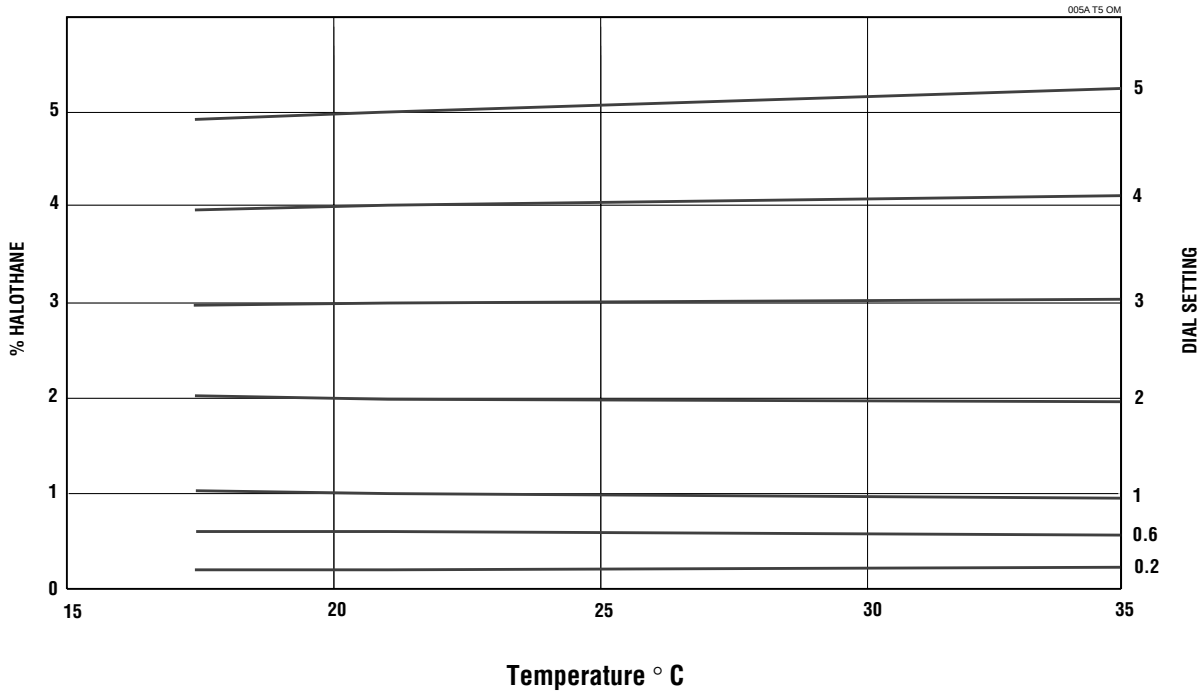


7.1.2 Fluotec 5%

Effect of Flowrate at 21 ± 2° C with oxygen flowing

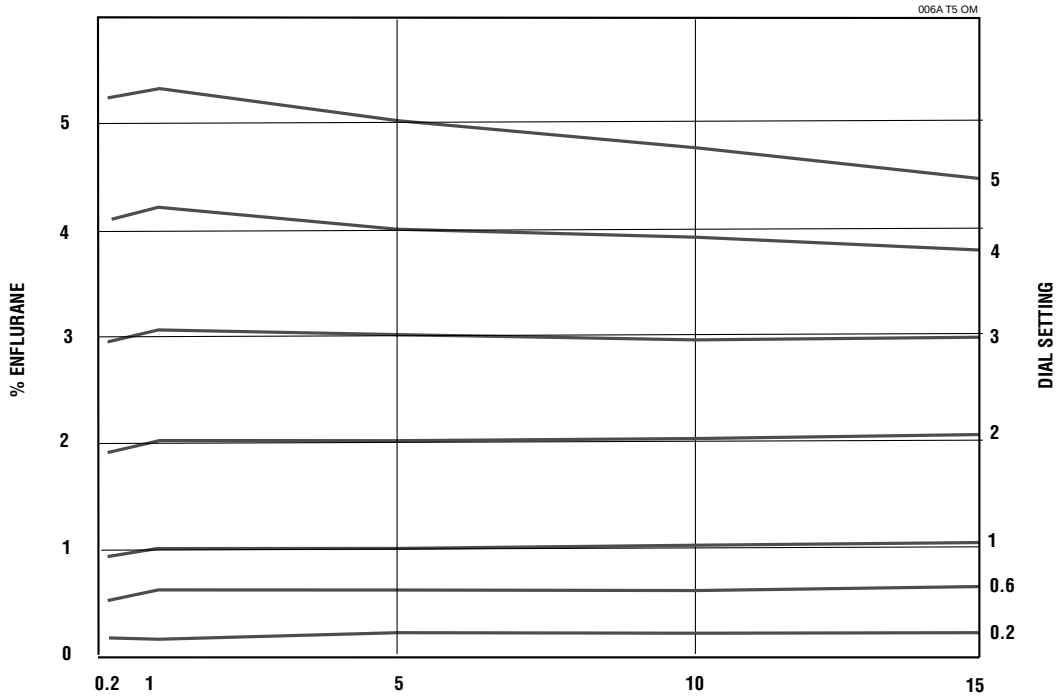


Effect of Temperature at 5 litres/minute oxygen flow

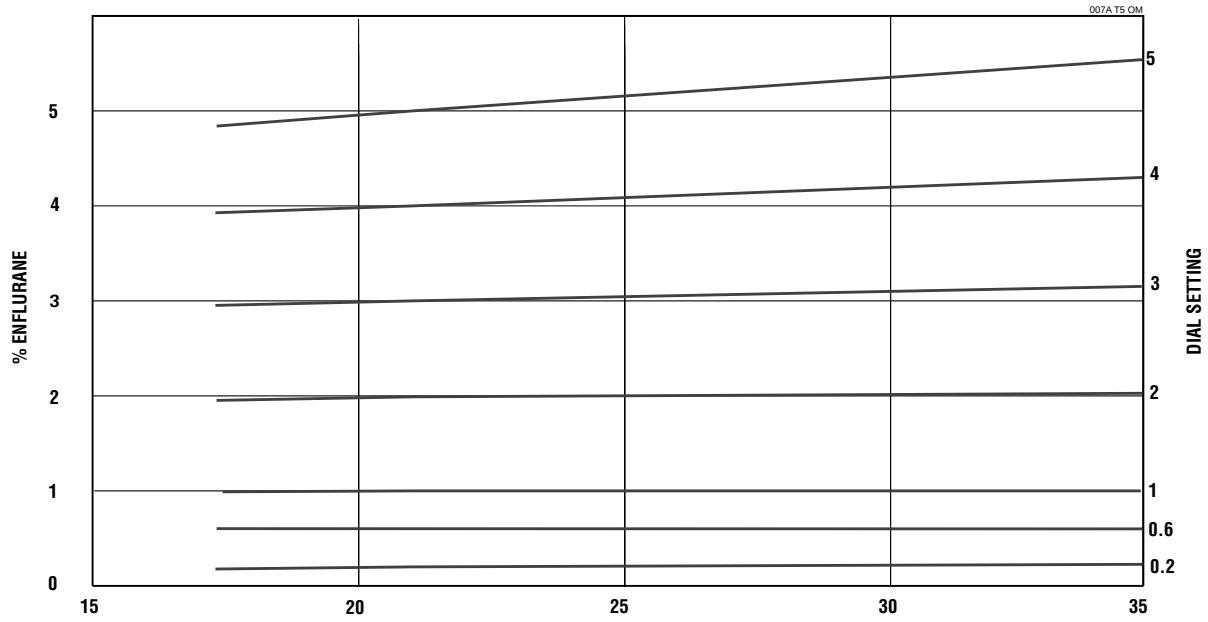


7.1.3 Enfluratec 5%

Effect of Flowrate at 21 ± 2° C with oxygen flowing

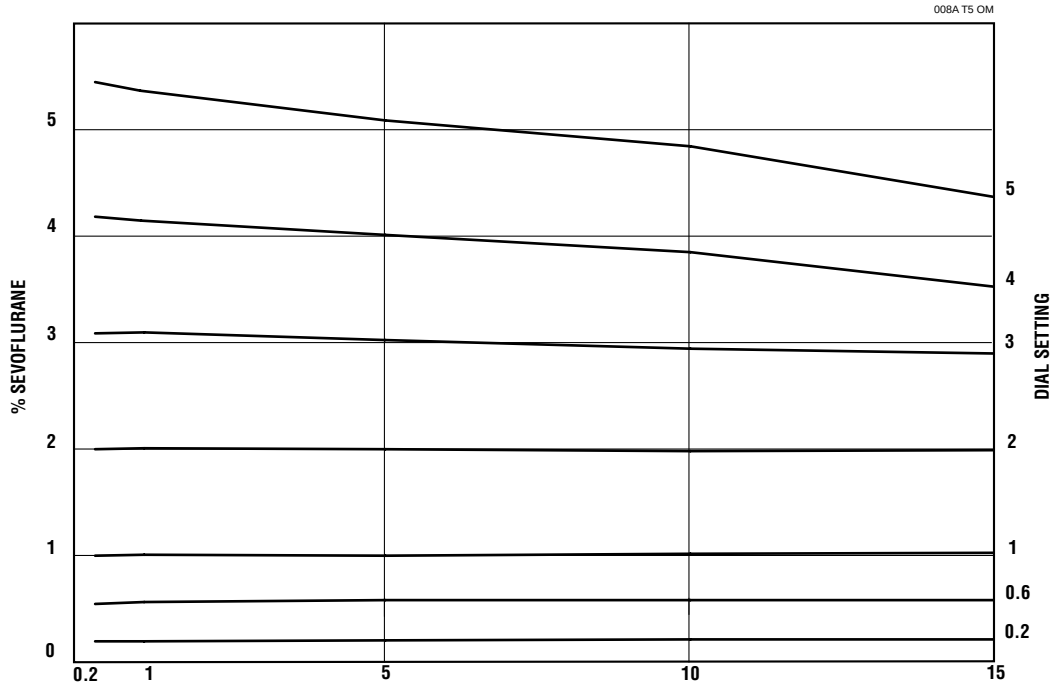


Effect of Temperature at 5 litres/minute oxygen flow

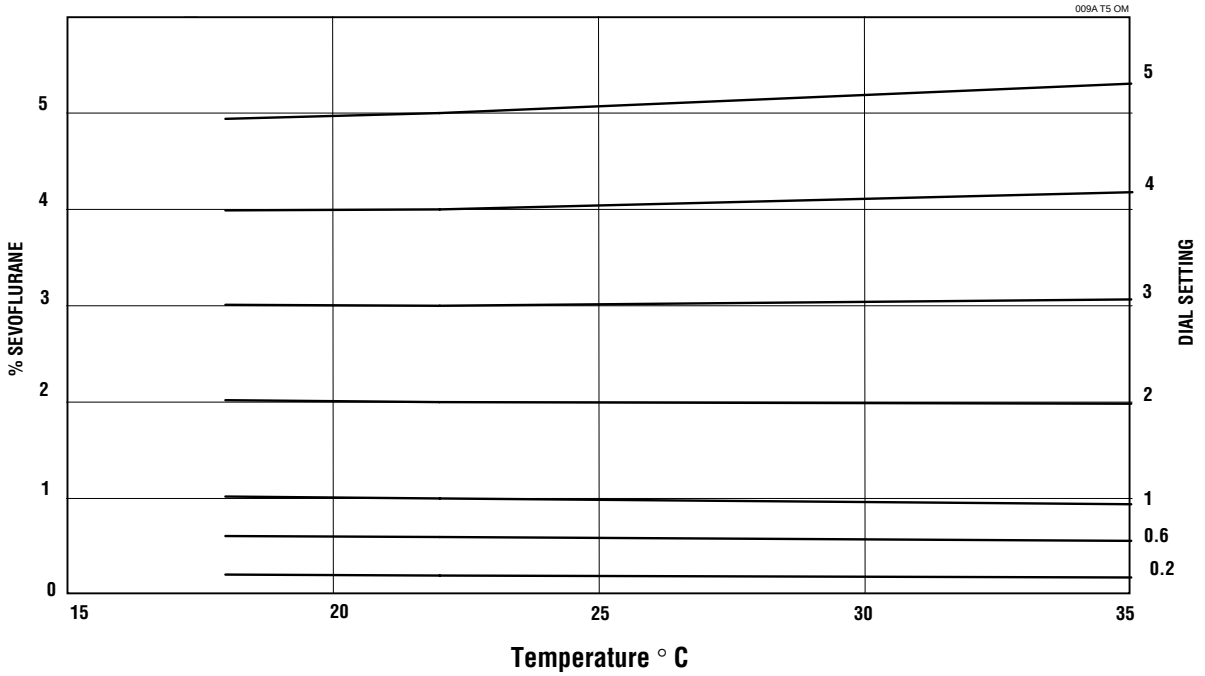


7.1.4 Sevotec 5%

Effect of Flowrate at 21 ± 2° C with oxygen flowing

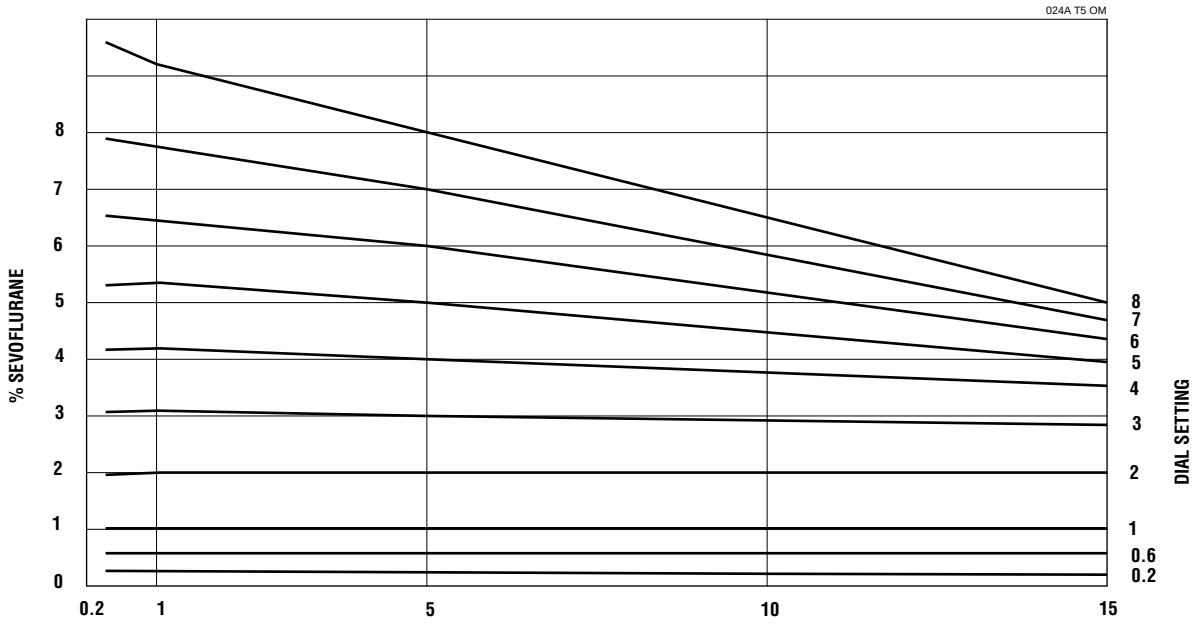


Effect of Temperature at 5 litres/minute oxygen flow

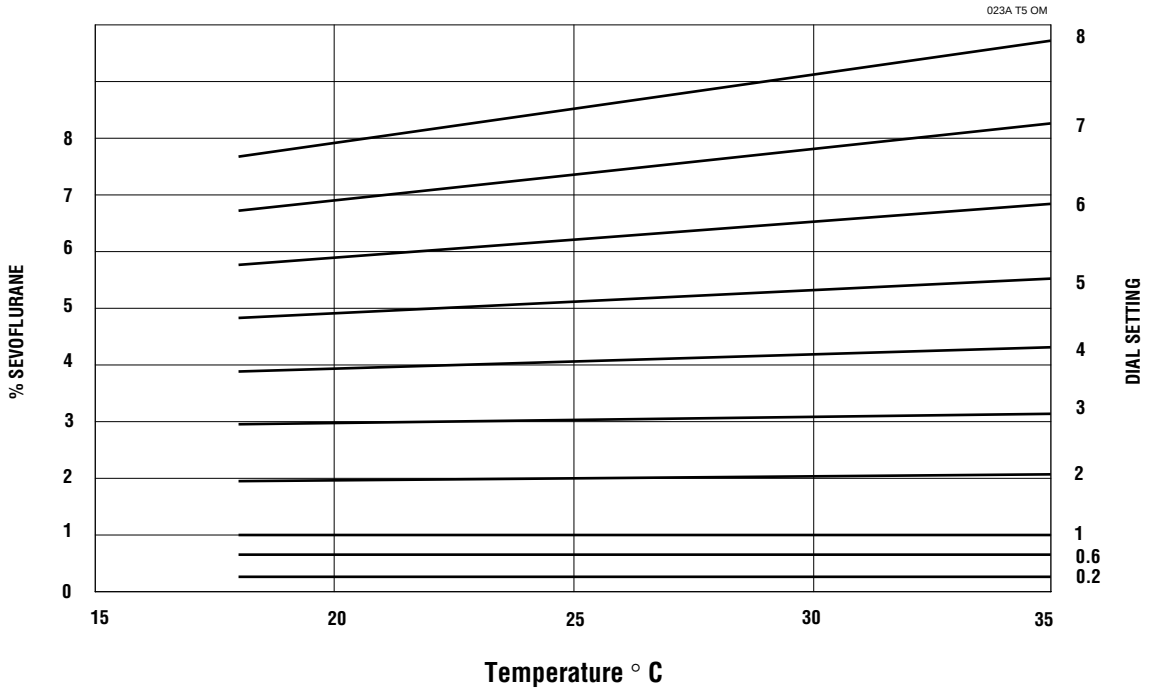


7.1.5 Sevotec 8%

Effect of Flowrate at 21 ± 2° C with oxygen flowing



Effect of Temperature at 5 litres/minute oxygen flow



7.2 Effects Of Variables

7.2.1 Anaesthetic Agent Consumption

7.2.1.1 Isoflurane, Enflurane And Halothane

The rate of consumption of anaesthetic agent depends primarily on flowrate and vapour output concentration. As an approximate working figure, 1 millilitre of liquid anaesthetic is required to provide 200 millilitres of vapour.

The approximate hourly consumption of anaesthetic agents can be expressed as 3 x % x F, where % represents the setting of the vaporizer output percentage and F represents the input flowrate in litres/ minute.

Example: If a vaporizer is set to deliver 2% at 6 litres/minute total gas input flowrate then the approximate rate of consumption = 3 x 2 x 6 = 36 ml/hour.

The figures are approximate and are intended for general guidance only.

7.2.1.2 Sevoflurane

The rate of consumption of anaesthetic agent depends primarily on flowrate and vapour output concentration. As an approximate working figure, 1 millilitre of liquid anaesthetic is required to provide 200 millilitres of vapour.

The approximate hourly consumption of anaesthetic agents can be expressed as 3.3 x % x F, where % represents the setting of the vaporizer output percentage and F represents the input flowrate in litres/ minute.

Example: If a vaporizer is set to deliver 2% at 6 litres/minute total gas input flowrate then the approximate rate of consumption = 3.3 x 2 x 6 = 39.6 ml/hour.

The figures are approximate and are intended for general guidance only.

7.2.2 Temperature

The effects of variation in temperature are normally negligible at commonly used combinations of dial setting and ambient temperature.

If the vaporizer temperature is above the range shown on the performance curves, the vaporizer output may be unpredictably high, particularly if the temperature of the agent approaches the agent boiling point specified by the agent Manufacturer.

If the vaporizer temperature is below the range shown on the performance curves, the vaporizer output may be lower than expected.

To help to avoid inaccuracies due to extreme temperatures, before using the vaporizer it must be allowed to attain a temperature within the range shown on the performance curves.

7.2.3 Barometric Pressure

Vaporizers are graduated in % v/v at 760 mm Hg. If the ambient pressure changes the % v/v changes, so that at an ambient pressure P mm Hg the delivered percentage (D% v/v) is calculated as follows:

Equation 1: $D = \frac{\% \times 760}{P}$ where % is the nominal setting of the vaporizer.

To obtain a consistent depth of anaesthesia when gross changes of barometric pressure occur, the % v/v must be changed in inverse proportion to the barometric pressure.

The vaporizer automatically makes this % v/v change and for practical clinical purposes the effects of barometric pressure can be ignored.

7.2.4 Back Pressure (Steady)

7.2.4.1 Low And Moderate Pressures

The vaporizer cannot distinguish between pressures at the outlet due to barometric pressure and pressures in excess of barometric due to steady back pressures applied by downstream components. Equation 1 therefore applies with the term P now being the absolute pressure at the outlet, that is, barometric pressure plus back pressure. Steady back pressure reduces the % v/v.

Currently it is unlikely that the steady back pressure imposed by commonly used downstream components, other than some ventilators, exceeds 30 mm Hg at commonly used flowrates. Back pressures as high as 30 mm Hg would reduce the delivered % v/v, at 760 mm Hg barometric pressure, to the following:

Equation 2: $\frac{760}{790}$ = 0.96 of what would otherwise be expected.

Under normal clinical circumstances effects of this magnitude can be ignored.

7.2.4.2 High Pressures

⚠ **Warning: Pressures in excess of 400 mm Hg must not be imposed on the vaporizer since pressures of this magnitude may overcome the internal pressure balance and cause a variation in output.**

7.2.5 Back Pressure (Fluctuating)

Fluctuating back pressures may be imposed on the vaporizer by downstream components and/or assisted or controlled ventilation to the patient. These fluctuating back pressures can affect the vaporizer and increase the concentration by intermittently altering the pressures, and hence the flow distribution, within the vaporizer.

The greatest effects are observed at combinations of very low flowrates and low dial setting with large and rapid pressure fluctuations. The effects become progressively less important as the dial setting and flowrate increase and the magnitude and rate of cycling of the pressure fluctuations decrease.

7.2.6 Carrier Gas Composition

Small effects on the output can occur when the carrier gas composition is changed. These effects may either be transient, arising from the varying solubility of gases in anaesthetic agent, or steady, due to the variations in gas density and viscosity affecting the flow split within the vaporizer.

When either air or nitrous oxide at low flows is employed as the carrier gas, the output is depressed compared to the output when oxygen is the carrier gas. This effect is greatest when nitrous oxide is employed, but using nitrous oxide reduces the required inspired concentrations of volatile agent thereby mitigating the small depression in output from the vaporizer.

At high flows and low dial settings a small increase in output may be observed.

If the proportion of nitrous oxide passing into the vaporizer is increased, a temporary decrease in vapour output is obtained. Conversely, if the proportion of nitrous oxide is decreased, a temporary increase in output is obtained.

⚠ **Warning: Do not operate the vaporizer other than with dry medical gases.**

7.2.7 Time Out Of Service

If the anaesthetic machine on which the vaporizer is fitted is left for a period of time with no gases flowing, small concentrations may be detected at the machine outlet immediately after the gas flow is turned ON. This is a normal machine characteristic and is caused by residual vapour left in the machine from previous use.

When the vaporizer is turned from OFF after a period out of use, a brief high concentration may occur which rapidly stabilises to the set concentration within approximately 10 seconds at 5 litres/minute.

The preceding phenomena are normal characteristics of vaporizers. In use the volume of vapour involved is small compared to the volume of the breathing circuit.

7.2.8 Other Variables

Ambient temperature, input flowrate and duration of use can affect delivered concentration, particularly when the vaporizers are used at extremes of the usual clinical range.

Note: Use of the vaporizer at high gas flows and high dial concentrations may affect the accuracy of delivered concentrations. Refer to Performance Curves in Section 7.1 for full information.

The valve design and temperature compensation system of Tec 5 Vaporizers reduces the effects to levels such that, under most clinical conditions, their effect on vaporizer performance is not clinically significant. The nominal performance characteristics should be consulted for further details.

8.0 Checking The Calibration

The performance of most vaporizers which are in clinical use can be confirmed by observing patient signs and consumption of anaesthetic agents. Some users may, however, wish to employ analysers either as a routine procedure or as part of an investigation to determine whether any abnormalities of performance have developed.

In order to help to achieve the reliability and consistency of performance of Tec 5 Vaporizers, Datex-Ohmeda use closely specified test conditions, test methods and detailed protocol in conjunction with training, experience and quality auditing systems. For these reasons the full programme necessary to help to ensure that a vaporizer complies with Datex-Ohmeda specifications cannot practicably be carried out in a field situation.

The following points must be considered when any measurements are being carried out on vaporizers to assist in determining whether any abnormalities of performance have developed.

1. In order to predict the concentration that the vaporizer can be expected to deliver, the detailed nominal performance data and the preceding comments must be taken into account.

2. The method of test used must not be such that it bears little relation to normal conditions of clinical use.

3. Any sampling techniques used must be such as to ensure the following:
   a) The sample is fully representative of the vaporizer output, which may not be a homogeneous mixture at the vaporizer outlet.
   b) The absorption of agent by any connecting tubing is negligible.

4. If a number of vaporizers are being examined at the same time the probability of all of them being consistently in error is so remote as to be negligible and the cause of any apparent error probably lies in the test method employed.

5. Consistent and reproducible analytical techniques must be used.

6. If unexpected results are obtained it is a wise precaution to repeat the observation because the vaporizer may be more reliable than the techniques used to observe its performance.

7. If unexpected results occur it is also worthwhile checking for sources of error such as the flowmeter, leaks or absorption by adjacent components.

8. Full account must be taken of any extraneous effects on the analyser which may arise from changes in the carrier gas composition.

9. If the anaesthetic machine on which the vaporizer is fitted is left for a period of time with no gases flowing, sensitive analysers may detect small concentrations of agent for a short time at the machine outlet after the gas flow is turned ON with the vaporizer turned OFF. This is a normal machine characteristic caused by residual vapour left in the machine from previous use.

10. When the vaporizer is turned from OFF to 0% or above after a period out of use, an increased concentration may occur which rapidly stabilises to the set concentration within approximately 10 seconds at 5 litres/minute flow.

11. At the 0 % setting it is not abnormal for small steady concentrations to be observable on sensitive analysers.

9.0 Analytical Techniques

For field checking of the state of calibration, many techniques and analysers are available. Datex-Ohmeda would not recommend any one technique or analyser in preference to another, but the calibration and reliability of analysers must be realistically considered and account must be taken of errors of use.

The following method of checking can be used where special equipment is not available or where a secondary check of analysers is desired. The characteristics of the vaporizer are such that if the vaporizer is satisfactory at one dial setting it should be satisfactory at all other graduations.

1. Ensure that the vaporizer is at least half full and has been at an ambient temperature ±02°21C for at least three hours.

2. With the vaporizer securely mounted, drain the vaporizer as detailed in Section 4.6 and after draining ensure that either the drain plug and the filler cap are both securely tightened or the port valve is fully closed and the locking clamp is in the up position, as appropriate.

3. Check that the control dial is turned OFF and then carefully and quickly pour a measured 50 millilitres of agent into the vaporizer without spilling.

4. Leave the vaporizer at a nominal temperature of ±212° C for one hour to help to ensure that the temperature has stabilised.

5. Set the flowrate to 5 litres/minute oxygen.

6. Turn the control dial to 2%, note the time and check that the flowrate is still 5 litres/minute. Readjust the flowrate as necessary.

7. Leave the vaporizer at this setting for 30 minutes. Periodically check and adjust the flowrate as necessary. Turn the vaporizer OFF and turn the oxygen OFF.

8. Drain the vaporizer as detailed previously in Instruction 2 and measure the amount of liquid drained off. The amount of liquid consumed should be as follows:

Fluotec	13.5 millilitres
Enfluratec	15.5 millilitres
Isotec	15.5 millilitres
Sevotec	16.6 millilitres

Appropriate action must be taken to handle the exhaust gases and spillage.

It must be appreciated that the preceding method is designed to be a quick and easy check of vaporizer operation and that the method is somewhat imprecise. Nevertheless, it would be unusual for the measured liquid consumption to vary by more than 25% of the preceding values.

10.0 Specification

10.1 Calibration

Vaporizers are calibrated at 21C using an oxygen carrier gas at a flow of 5 litres/minute and they are temperature, flow and pressure compensated within the specified operating range.

10.2 Resistance To Gas Flow With Vaporizer Out Of Circuit

Resistance	Vaporizer Setting	Flow rate	Temperature
10 -15 cm wg	ON + 0%	5 litres/minute, Oxygen	21 ± 2° C

10.3 Liquid Capacity

The amount of liquid to fully charge a vaporizer with dry wicks = 300 millilitres (nominal).

The amount retained by the wick system = 75 millilitres (nominal).

5% Vaporizer
The amount of liquid to fill the vaporizer from the minimum to the maximum mark = 170 milliliters (nominal).

8% Vaporizer (Sevotec)
The amount of liquid to fill the vaporizer from the minimum to the maximum mark = 137 milliliters (nominal).

10.4 Weight And Dimensions

Weight	Height	Depth	Width
7.0 Kg	250 mm	164 mm	110 mm

10.5 Environmental Conditions

Operating temperature Range = 16 to 35°C

Storage temperature range = –40 to +65°C

Note: The vaporizer packaging should be protected from condensation.

10.6 Performance

Accuracy at 5 litres/minute O_2 @ 21°C ± 2°C:

Vaporizer 5% ±0.25% of delivered agent or
±15% of dial setting (whichever is greater).

Vaporizer 8% ±0.4% of delivered agent or
±15% of dial setting (whichever is greater).

11.0 Warranty

Such warranties are extended only with respect to the purchase of this Product directly from Datex-Ohmeda or Datex-Ohmeda's Authorized Dealers as new merchandise and are extended to the first Buyer thereof, other than for purpose of resale.

For a period of three (3) years from the date of original delivery to the first Buyer or to Buyer's order, this Product, other than its expendable parts, is warranted against functional defects in materials and workmanship and to conform to the description of the Product contained in the Operation and Maintenance manual and accompanying labels and/or inserts, provided that the same is properly operated under conditions of normal use, that regular periodic maintenance is performed and that replacements and repairs are made in accordance with the instructions provided. This same warranty is made for a period of thirty (30) days with respect to expendable parts.

The foregoing warranties shall not apply if the Product has been repaired or serviced other than by Datex-Ohmeda or other than in accordance with written instructions provided by Datex-Ohmeda, or altered by anyone other than Datex-Ohmeda, or if the Product has been subject to abuse, misuse, negligence, or accident.

Datex-Ohmeda's sole and exclusive obligation and the Buyer's sole and exclusive remedy under the above warranties is limited to repairing or replacing, free of charge, at Datex-Ohmeda's option, a Product, which is confirmed as being defective by Datex-Ohmeda following the Buyer's notification to Datex-Ohmeda in accordance with the instructions contained in the Service Policy section of the Operation and Maintenance Manual, not later than seven (7) days after the expiration date of the applicable warranty**Datex-Ohmeda shall not be otherwise liable for any damages including but not limited to incidental damages, consequential damages, or special damages.**

There are no express or implied warranties which extend beyond the warranties herein above set forth. Datex-Ohmeda makes no warranty of merchantability or fitness for a particular purpose with respect to the Product or parts thereof.

Vaporizers which include an Abbott List No. on the rear of the interlock block were initially distributed by:

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Tec 5 Vaporizer
O & M Manual, English
1105 0100 000
08 99 B Madison
Printed in USA
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